EXHIBIT M

FOR THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION
Master File No. 2:12-MD-02327
MDL NO. 2327

THIS DOCUMENT RELATES TO:

TONYA AND GARY EDWARDS
vs.
ETHICON, INC., ET AL.,
(Case No. 2:12-cv-09972)

JOSEPH R. GOODWIN
U.S. DISTRICT
JUDGE

and

JO HUSKEY AND ALLEN HUSKEY
vs.
ETHICON, INC., ET AL.,
(Case No. 2:12-cv-05201)

DEPOSITION OF SCOTT A. GUELCHER, PH.D.

Nashville, Tennessee

March 25, 2014

Reported by Marilyn Morgan, LCR #235, CCR #0174

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The deposition of SCOTT A. GUELCHER, PH.D., taken on behalf of the Defendant and taken pursuant to notice on March 25, 2014, beginning at approximately 9:19 a.m., at 150 3rd Avenue, South, Nashville, Tennessee, pursuant to stipulations of counsel.

S T I P U L A T I O N S

It is agreed that the court reporter, being a notary public for the State of Tennessee, may swear the deponent, take the deposition on the Stenograph shorthand machine and afterwards reduce the same to typewriting when it may be used for all purposes provided by the Federal Rules of Civil Procedure governing depositions.

I N D E X

E X H I B I T S

SCOTT A. GUELCHER, PH.D., after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. THOMAS:

Q. Good morning, Dr. Guelcher. It's Guelcher; is that correct?

A. That's right.

Q. I introduced myself to you before the deposition. My name is David Thomas. I represent Ethicon. I'm going to ask you a number of questions today about your expert reports in the Ethicon matters; fair enough?

A. Yes.

Q. I see that you have before you two notebooks. What's in the notebooks?

A. So one of these notebooks is the report with -- the first report that was filed with the reliance documents from that. And the second notebook is another notebook of support documents.

Q. We'll both be doing that today so take your time and don't worry about it.

The second notebook that you referred

Page 6

to is additional support documents?
A. Yes, that's right.
Q. Do the additional support documents in the second notebook relate to the first report?
A. Yes.
Q. Do the two notebooks that you have in front of you represent the total of the reliance materials for the reports that you've provided in this matter?
A. Yes.
(Exhibit 1 was marked.)
Q. (By Mr. Thomas) Let me show you what I've marked as deposition Exhibit No. 1. Deposition Exhibit No. 1 is what was provided to us as the Rule 26 expert report for you in this matter.
When you referred to your first notebook as having the report and reliance materials, is Exhibit No. 1 the report to which you're referring?
A. Yes.
Q. On -- at the end -- I'm sorry. Exhibit B to Exhibit No. 1 is a list of

Page 7

reliance materials attached to your report?
A. Yes.
Q. Do you have that?
A. Yes.
Q. Is everything that is in the two notebooks that you've just identified for the record contained within the reliance materials, to your knowledge?
A. Yes, I believe so.
Q. Are there documents in this reliance list that are not contained in the two notebooks that you brought with you today?
A. I don't think so.
Q. Okay. Was it your intention when you brought the two notebooks that you've identified earlier today that you brought with you all the documents upon which you relied for the formulation of your opinions in the case?
A. Yes.
Q. Just for the record, the first notebook that you identified it has a title on it that says In Re: Boston Scientific Corporation, Product Liability Litigation, Expert Report of Scott Guelcher, Ph.D.

Page 8

A. Yes.
MR. THOMAS: We'll mark that as Exhibit No. 2.
(Exhibit 2 was marked.)
Q. (By Mr. Thomas) This was the first notebook to which you referred for your expert report and your reliance materials; fair?
A. Yes.
(Exhibit 3 was marked.)
Q. (By Mr. Thomas) Deposition Exhibit No. 3 is a second notebook of documents that you brought with you that are your reliance materials for your expert report in the Ethicon case?
A. Yes.
Q. It's your testimony that the documents in Exhibits 2 and 3 are the total of the reliance materials for your expert report which we've marked as Exhibit 1?
A. Yes.
Q. All right. Did you bring with you any other materials for your deposition today?
A. No.
Q. Did you bring any billing records

Page 9

with you today?
A. No. Dr. Dunn has those. That's subcontracted through Dr. Dunn.
Q. Did you prepare billing records that you gave to Dr. Dunn?
A. I have sent him some billing records, yeah. But I don't have those with me. Dr. Dunn has them.
Q. Is there a reason why you didn't bring those with you here today?
A. I haven't been bringing them to depositions. So everything is billed through him. So I don't have them with me.
MR. THOMAS: Is there a reason why he hasn't produced those today?
MR. JACKSON: It was my understanding he didn't have them, that they were all in the custody of Dr. Dunn.
(Exhibit 4 was marked.)
Q. (By Mr. Thomas) Let me show you what's been marked as deposition Exhibit No. 4. Deposition Exhibit No. 4 is a notice of your deposition for today as well as a document rider that requests that you bring certain

Page 10

documents with you to the deposition. Did you review that in advance of your deposition?
A. Briefly.
Q. What did you do when you reviewed it? For what purpose did you review it?
A. To pull the documents together.
Q. And I believe you've told me the only documents that you've brought with you to the deposition today are the ones that we've marked in the notebooks of Exhibits Nos. 2 and 3?
A. That's right.
Q. Were there other documents that are responsive to Schedule A on Exhibit No. 4 that you didn't bring with you?
MR. JACKSON: I'm just going to note that we have pending objections to several of these scheduling requests.
MR. THOMAS: That's fine.
A. Let me look at this for a minute.
So I have provided an opinion on other pelvic mesh cases, but I did not bring that information with me because of the consulting with the attorneys. I think everything else is here, just looking at this.

Page 11

Q. (By Mr. Thomas) Let's look at Paragraph 1 of Exhibit 1, Schedule A, all documents related to fees, billing, and/or time spent in connection with your opinions.
How do you keep your time in this case?
A. I send activity reports to Dr. Dunn, and then he -- I must have misunderstood this. It's all billed through Dr. Dunn's company. So I send everything to him in the form of weekly activity reports and monthly invoices.
Q. Tell me the form that the weekly activity reports take.
A. It's a table that lists the hours that I worked per day, the specific time of the day that I worked on it, and then a brief description of the activity.
Q. And is this a report that you submit to Dr. Dunn on a weekly basis?
A. Usually. The reports are all -- it's a weekly summary.
Q. Is this a computer-generated report or a hand-generated report?
A. It's a -- I do it in Microsoft Word.

Page 12

Q. Do you have notes of the time that you spent that you transfer over to Microsoft Word?
A. I keep it on my calendar.
Q. And is your calendar a hard copy calendar?
A. It's electronic on my phone.
Q. And the time that you have on your electronic calendar on your phone is transferred over to your Microsoft Word report that you send to Dr. Dunn on a weekly basis?
A. That's right. Yes.
Q. And the report that you provide to Dr. Dunn identifies the day that you worked?
A. It identifies the day, the time of day, and the number of hours and the activity.
Q. Is that a form that you prepared or a form that Dr. Dunn provided to you?
A. It's a form that I had from other cases, other consulting, I should say.
Q. Other consulting with Dr. Dunn or consulting you've done individually?
A. Consulting I've done individually with other companies.

Page 13

Q. Are the weekly activity reports that you submitted to Dr. Dunn on your computer presently?
A. I think so. I don't think I deleted those off my computer.
Q. Is that something you could have sent to us today so we could --
A. I can. Like I said, in the past, I've not -- Dr. Dunn just had those, and I just missed it.
Q. Okay.
A. I can send them to you.
Q. Yeah. I would like to be able to ask questions about those today. So to the extent we can get those sent over here and printed out and used in the deposition --
A. I can do that.
MR. JACKSON: Do you have somebody who can log into your computer and get these? It might be easier just to have Dr. Dunn produce everything today. I can probably have them do that.
MR. THOMAS: That would be great.
THE WITNESS: I would be more

Page 14

comfortable for him doing that because he does the actual billing. That's why I was confused. But I think if he can send the reports, it would be better because I don't know that I've -- I mean, I send them to him and I --

MR. JACKSON: It may be that he was deposed prior to you previously, so it didn't matter.

THE WITNESS: That would be the most accurate version of what's available.

MR. THOMAS: Let's go off the record a second.

(Discussion off the record)

(Ms. Lewis joined the deposition by teleconference.)

MS. LEWIS: This is Christina Lewis. I'm with the Mueller Law Office, and we represent Mr. and Mrs. Edwards in this case.

And I would like an agreement from defense counsel that all objections by counsel for Huskey are the same as us. If we can have that agreement, I'll put my

Page 15

phone on mute so that I don't disrupt the deposition too much.

MR. THOMAS: That's fine with me.

MS. LEWIS: Thank you so much, and I apologize for the confusion.

MR. THOMAS: Not a problem.

Q. (By Mr. Thomas) Have you requested that Dr. Dunn supply those activities records?

A. Yes. He's not in his office, but he's going to call me when he gets there. If he'll e-mail them to me, I can get them printed out.

Q. Very good.

Dr. Guelcher, you testified a moment ago that you have consulted with attorneys on matters involving other mesh products; is that fair?

A. Yes.

Q. How many?

A. Three other products.

Q. And what are the manufacturers of those products?

A. American Medical Systems and Boston Scientific.

Page 16

Q. Okay. And then you've consulted with attorneys with respect to Ethicon products?

A. Yes.

Q. For a total of three?

A. Ethicon would be the fourth product. There are two AMS products.

Q. Okay. And have you given deposition testimony in the AMS cases?

A. One of the AMS cases and the Boston Scientific case.

Q. So have you given a total of two depositions?

A. Yes.

Q. What is the product at issue in the AMS case where you've given a deposition?

A. I believe it was the SUI.

Q. And what is the product at issue in the Boston Scientific case where you've given a deposition?

A. There were several products. I can't remember the names right now. Pinnacle maybe. There were five of them, but I can't remember all the names.

Q. For what application were those

Page 17

products used? For the same application?

A. Same application.

Q. For stress urinary incontinence?

A. Yes, I believe so.

Q. When were you first contacted about providing expert opinion with respect to Ethicon?

A. With respect to Ethicon would have been -- I don't remember the exact date. Maybe a month ago.

Q. How were you contacted?

A. By the attorneys at Wexler.

Q. Prior -- is it your practice when you get contacted to make notations in your activity log about contacts with counsel?

A. I'm not sure what you mean.

Q. Would we be able to go back and look at your activity reports that you have already identified that Dr. Dunn is going to give to us to find out when you were first contacted about this litigation?

A. In this case, I believe that would be -- that information would be in the activity report.

Q. Okay.
A. I believe.
Q. Were you contacted directly about providing expert opinions with respect to Ethicon, or did they go through Dr. Dunn?
A. It came through Dr. Dunn.
Q. And were you on a conference call with Dr. Dunn and counsel for plaintiffs in the case? Is that how you first got brought into the case?
A. No. Dr. Dunn called me in the evening and we discussed it.
Q. And what did Dr. Dunn tell you?
A. That the attorneys at Wexler Wallace wanted us to write an expert report for the Ethicon case.
Q. And did you and Dr. Dunn discuss the details of the scope of the expert report that you were preparing for the Ethicon case?
A. Yes.
Q. And tell me what you discussed during that call about the scope of the report.
A. Well, the scope of the report would primarily be teaching with respect to the

oxidation of polypropylene. We didn't have any samples. So it was all -- the report was essentially based on literature and documents from Ethicon about the oxidation of polypropylene.
Q. Did you divide responsibilities for the report during the call?
A. Dr. Dunn and I wrote separate reports. My report focused more on oxidation of polypropylene, particularly the response in the body.
Dr. Dunn's area of expertise is in product design, polymer science. So he addressed issues more related to safety analysis, those types of questions.
Q. Prior to the conversation that you had with Dr. Dunn about a month ago concerning this potential expert report, had you studied Ethicon mesh products at all?
A. No, I wouldn't say studied. I was familiar that the products existed because of the other litigation, but I had not studied Ethicon products in particular.
Q. So is it fair to understand that when

Dr. Dunn contacted you about preparing this expert report for use in this litigation, that you then began to -- your understanding of the Ethicon mesh products used to treat stress urinary incontinence?
A. A detailed understanding -- I had been studying the effects of in vivo polypropylene oxidation for some time, maybe six months prior to that. But the details of the Ethicon mesh started at the time I talked to Dr. Dunn.
Q. And the work that you did on the -- the six months work that you just discussed that you did was with respect to the meshes of other manufacturers?
A. With respect to the meshes of other manufacturers and also the oxidative degradation of polypropylene in general.
Q. Was the work that you did with respect to the Ethicon SUI mesh products different from the work that you did analyzing the AMS products or the Boston Scientific products?
A. It was different in the sense that we

didn't have samples, either materials as made or materials that had been explanted from the body. We didn't have those samples.
So we focused in the reports more on the literature, internal documents, more on the oxidative degradation of polypropylene.
Q. Have you ever analyzed an Ethicon mesh used for the treatment of stress urinary incontinence?
A. I have not. I don't have the sample.
Q. Have you ever analyzed an explant of mesh manufactured by Ethicon for the treatment of stress urinary incontinence?
A. No, not to my knowledge.
Q. Have you ever requested to analyze a mesh manufactured by Ethicon for the treatment of stress urinary incontinence?
A. Not to my knowledge. But a lot of the product testing was done by Dr. Dunn.
Q. Have you ever requested to a mesh explant manufacturer for Ethicon, for the treatment of stress urinary incontinence, for the purposes of your own analysis?
A. I have not done that directly.

Page 22

Dr. Dunn had some materials from manufacturers and I don't remember exactly what. But personally I have not requested samples.
Q. Did you have conversations with Dr. Dunn about the availability of mesh samples for testing?
A. I think in this case, to the extent that we didn't have them.
Q. My question was, did you have conversations with Dr. Dunn about the availability of mesh samples for testing?
A. I mean, we discussed it. But the problem was we didn't have the samples. So they weren't available.
Q. Did you request samples to conduct testing?
A. I did not. I don't know what he did. But I know that the time was short between when we had to get the report submitted and when the request came. So there was also a time constraint. There wasn't time to do it.
Q. Now, did the work that you did in the AMS and Boston Scientific litigation follow the same pattern in terms of what you did for those

Page 23

cases?
A. Well, in the AMS and Boston Scientific studies, we had exemplars and we had in some cases explanted materials. There may have been materials from Ethicon. I just don't remember because it wasn't part of that specific case. And Dr. Dunn did that testing, and he would know.
Q. Okay. In the AMS litigation, what kind of testing did you conduct on AMS exemplar mesh?
A. So can I talk with -- this or other cases, I don't know how much detail I can disclose on this. These are other cases that are by protective court order, so I don't know what I can say or not say in terms of the details.
Q. I'm asking now only what kind of testing that you performed, not what the results of those tests were.
A. Right. But I don't know that -- because it's a protective order, I don't know that I could even disclose the tests that we did because it was somebody else's material on

Page 24

a different case. So I guess I'm concerned about disclosing something I'm not allowed to disclose.
Q. Would you like to consult with counsel?
A. I would, if that would be okay.
Q. Just for the record, just for your benefit, I'm going to want to know all the kinds of tests that were conducted on the AMS and Boston Scientific meshes and the purposes of those tests.
If he's not going to be permitted to answer that, then we'll figure out the next path to take.
MR. JACKSON: The question is how far the protective orders go in the state courts that are involved. So Boston Scientific state court litigation was in Delaware and Massachusetts. And the AMS litigation was at the MDL level.
MR. THOMAS: Just so you know, I'm not going to argue with you about it. Either you're going to let him answer or you're not. I am going to go to court and

Page 25

seek to get the answers because I think it's very important to what's going on here.
So either he's going to answer or he's not. I'm not going to argue with you about it.
MR. JACKSON: I think the questions he's asked, you need to answer them at this point.
A. Okay. So could you repeat it? I have lost track.
Q. (By Mr. Thomas) What kinds of tests did you conduct on the exemplar meshes for AMS?
A. So for AMS, we did gel permeations chromatography, GPC. I should say Dr. Dunn did all the testing. I'm telling you what I remember. So in some of this would be my report so it's not an all inclusive list, but it's what I remember.
Q. Very good.
A. We did GPC. I know he took a number of photographs under the microscope.
Q. Light microscopy or SCN?
A. Light microscopy. I think there was

Page 26

-- well, I don't know about the SCN. I can't remember.

We also did x-ray photoelectron spectroscopy or XPS. That's a surface method where we can detect products of oxidative degradation on the surface.

We also did FTIR. Again, Dr. Dunn did all of these studies I know for the AMS, I believe for the Boston Scientific as well. Ethicon, I can't remember. It's not in my report so I don't -- and Dr. Dunn did it. So I don't remember what we did there.

Q. The purpose of the GPC testing is to do what?

A. Measure the molecular weight.

Q. What does molecular weight tell you in the context of oxidation?

A. Well, if the oxidation is sufficiently severe. So oxidation comes from the surface inward. If the oxidative degradation is severe enough, say during processing or after implantation, you could see a reduction in molecular weight which can correlate with reduction in ductility and

Page 27

embrittlement. So that was the GPC measurement.

Q. For what purposes did you take the photographs by light microscopy?

MR. JACKSON: Object to the form.

A. Just a visual representation of the mesh.

Q. (By Mr. Thomas) For what purpose was the XPS testing conducted?

A. The purpose of the XPS was to look for carbonyl and hydroxyle groups on the surface which are products of oxidative degradation.

Q. What is FTIR?

A. Fourier transform infrared spectroscopy.

Q. And I believe you testified that Dr. Dunn conducted FTIR testing on both AMS and Boston Scientific meshes?

A. I believe that he did, but I'm more confident in the XPS data because that's what I specifically used in my reports. Dr. Dunn can speak to all the testing that was done. Those were all done by him.

Page 28

Q. In addition to the tests conducted on the exemplar meshes, were the same tests conducted on explanted meshes?

A. Only for one of the AMS cases. We had some explanted mesh and we did XPS on that mesh.

Q. For what purpose did you conduct XPS testing on the AMS explanted mesh?

A. To identify the presence of carbonyl and hydroxyle groups similar to the exemplars.

Q. When you tested the explanted mesh from AMS, was it necessary to prepare that mesh explant for testing?

A. The preparation of the explant was done by Dr. Iakovlev, who is at the University of Toronto.

Q. Did you or Dr. Dunn have any involvement in consulting with Dr. Iakovlev about the preparation of the explant for XPS testing?

A. We did.

Q. And tell me about your conversations with Dr. Iakovlev about the appropriate way to prepare this sample for analysis.

Page 29

A. Well, we had it shipped to us wet. Dr. Iakovlev --

Q. Let me stop you there. When you say shipped wet, what do you mean by that?

A. It was in buffer, I believe, saline buffer. I can't remember the details.

Q. Was the mesh when you received wet in Formalin?

A. No, I don't think so.

Q. Was there a reason why you did not want it in Formalin?

A. Well, some of Dr. Iakovlev's samples were processed in Formalin for histology. Now formalin is compatible with polypropylene. It's known that you can look it up. Dr. Iakovlev has run controls on pristine meshes, but we felt for this purpose to have it in saline would introduce less questions regarding the analysis.

Q. Why did you use saline instead of Formalin?

A. Saline is typical physiological. It's a buffer that's used often to mimic body fluids.

Page 30

Q. What concerns did you have about any impact Formalin may have on the sample that you were going to test?
A. We didn't have any concerns because polypropylene and Formalin are compatible.
Q. At the time that you analyzed the mesh explant from AMS that you had shipped in saline, did you analyze the extent to which Formalin would interact with proteins on the surface of the mesh explant?
A. No. Dr. Iakovlev desiccated the explants manually, from what I remember. He removed extra tissue that he could find and then shipped them to us dry for the XPS testing.
Q. I'm sorry. I misunderstood your answer. I thought you told me a minute ago that you received the mesh explant wet.
A. Dr. Iakovlev did. He received the mesh explant from the hospital. He prepared the sample for XPS and then shipped it to us dry after he had removed the tissue from the sample.
Q. I see. Did -- how did Dr. Iakovlev

Page 31

clean the sample?
A. I can't remember the details. It was a different case, so I didn't review this. So how much detail again should I --
MR. JACKSON: If you can, answer the question.
A. In this case, I really can't remember exactly how he -- he did it. I know that he had some mesh samples that he had scraped and some that he had manually dissected just to remove the tissue. But it was all done in things like saline or dry.
To my knowledge, I can't remember any processing of Formalin. But I'm going on my memory, and it was a different case.
Q. All right. Was there any effort to test explanted meshes from the Boston Scientific litigation?
A. I'm not sure what you mean by "any effort." We didn't have the explant, so we couldn't do it.
Q. Did you request explants from Boston Scientific to conduct tests?
A. I believe we did. But then again,

Page 32

Dr. Dunn has been handling those types of requests.
Q. Going back to the AMS explant you and Dr. Dunn analyzed, you said you conducted XPS testing. Any other testing you conducted on that AMS explant?
A. No. I mean, the amount of sample is very small. Dr. Dunn may have done -- he may have done FTIR. I can't remember. But I think the samples are very small. That's one advantage of XPS, is that we can probe a very small surface.
So to my knowledge, what I can remember is we only did XPS on those.
Q. What was the goal of conducting the testing on the AMS explanted mesh?
A. It was to look for presence of hydroxyle and carbonyl groups on the surface that are associated with polypropylene degradation.
Q. And what do the hydroxyle and carbonyl groups tell you if you find them on these explanted meshes?
MR. JACKSON: Object to the form.

Page 33

A. Well, you can do a similar approach using FTIR that's in the literature where it tells you that -- polypropylene is a hydrocarbon. So there shouldn't be any carbonyl and hydroxyle groups. So if you see these species, it's an indication of oxidation of the surface.
This has been done by FTIR, also, in the past. But XPS, we believe, is more sensitive.
Q. More sensitive than what?
A. FTIR.
Q. In what respect is XPS more sensitive than FTIR?
A. XPS gives atomic percents, so percent carbon, percent oxygen, percent nitrogen. And it also provides details about the state of the bonding. So it can tell you whether there's bound oxygen on the surface.
Q. Why wasn't GPC testing conducted on the AMS mesh explant?
A. There wasn't enough material, and GPC takes quite a bit more material.
Q. In the hierarchy of tests, it

Page 34

provides you helpful information to understand the extent to which degradation may have occurred, where does GPC fit?

MR. JACKSON: Object to the form.

A. Well, I believe the GPC would be below XPS in priority because GPC is a bulk measurement. XPS is a surface measurement. Oxidative degradation proceeds from the surface inward. So XPS is going to provide more detailed information.

Q. (By Mr. Thomas) How does GPC compare to FTIR?

A. FTIR is also a method primarily for looking at the oxidized species on the surface. GPC is measuring the bulk molecular weight of the polymer.

Q. Which is more sensitive, FTIR or GPC?

A. I don't know if I could answer that. They measure different things. GPC measures molecular weight and FTIR is measuring chemical composition.

Q. Is it fair to understand that a molecular weight analysis is going to be more accurate than an FTIR analysis to understand

Page 35

the extent to which polypropylene is degraded?

A. I wouldn't agree with that -- the only way you could support that statement is if you could measure GPC of that actual degraded layer. But, again, that's going to be difficult.

GPC is essentially a volume average over the entire fiber. So it doesn't really tell you what's going on on the surface because it's averaged over the entire volume.

Q. Have you ever testified that molecular weight analysis is more sensitive to look at degradation than FTIR?

A. They measure different things. So GPC measures molecular weight. FTIR measures the surface composition. And FTIR is, I don't think is, as sensitive as XPS, but they just measure different things.

I think GPC is an important measure -- if you see degradation by GPC, that means it's even -- it's fairly degraded, if you're seeing loss in molecular weight.

But I wouldn't use the word sensitive. I would say XPS can tell you what's

Page 36

happening at earlier time points before you have a lot of molecular weight loss, and then GPC would actually measure that loss in molecular weight. So it's measuring something different.

Q. Do you agree with this statement: A molecular weight analysis is really going to be more accurate, I think, than to try to look for degradation than with the FTIR for these explanted meshes?

A. It depends on the context of the statement. I mean -- like I said, GPC is going to tell you whether there's a loss of molecular weight in the material. FTIR -- the problem with FTIR is it could be looking at -- you can't interpret it as directly as XPS in terms of the source of the carbonyl or the hydroxyle groups. And it has to be fairly far along in the degradation before you can see it.

Q. What has to be fairly far along in the degradation before you can see it? I didn't understand your answer. I'm sorry.

A. Well, I'm saying that FTIR, I think is -- XPS, you can see what's happening, I

Page 37

believe, at earlier time points than you could with FTIR because the peaks aren't always as resolved as well. XPS is, I think more precise.

Q. So is it your position that XPS is the best test method to understand the extent to which oxidation occurs on the surface of explanted meshes?

A. I would say that XPS can -- I think the advantage of XPS is it can predict what's happening at very early time points before there's molecular weight loss.

Molecular weight loss happens later in the process. Those carbonyl and hydroxyle groups will form on the surface earlier. So GPC is very effective for measuring molecular weight loss. I think what I'm saying here is that XPS can predict those events at very early time points before there's molecular weight loss. That's what I'm saying.

Q. What kind of equipment is necessary to conduct XPS testing?

A. Well, there's a specific instrument in XPS that's a high vacuum device. So you have to -- it's a fairly expensive instrument.

Page 38

Q. And how is that test conducted?
MR. JACKSON: Object to the form.
A. Dr. Bridget Rogers at Vanderbilt did the XPS testing. That's her area of expertise. The actual details of how the test is performed, she would be -- she's the one that did the testing for this. I basically talked with her about interpretation of the data.
Q. (By Mr. Thomas) Okay. How is XPS testing different from EDX testing?
A. Well, EDX, in my understanding, is more like SCM where you would look for specific atoms in the background. But my understanding is that XPS is more sensitive than EDX. That's why we did XPS.
Q. Did you conduct any EDX testing on any of the meshes you analyzed?
A. Not to my knowledge, but Dr. Dunn would be able to speak to that.
Q. The reason why you and Dr. Dunn conducted the tests that you did on the AMS and Boston Scientific meshes was to understand the extent to which these meshes may undergo oxidative degradation?

Page 39

A. Yes. We were looking for evidence of oxidative degradation. The advantage of XPS is that you can see what's happening at early time points, and it doesn't require a lot of sampling. And you can probe the surface with it. That's really the advantages of it.
Q. Okay. Dr. Guelcher, go back to a month ago or so when you were first contacted by Dr. Dunn about your work in this case, and you had this conversation with Dr. Dunn you just told me about, and you decided what work you were going to do and you didn't have any exemplars and you didn't have any explanted meshes. What did you do to acquaint yourself with the Ethicon product?
MR. JACKSON: Object to the form.
A. We reviewed papers on it, internal documents, published papers describing the product.
Q. (By Mr. Thomas) Are all the documents that you reviewed to familiarize yourself with the product in Exhibits 2 and 3?
A. Yes.
Q. Did you conduct your own literature

Page 40

search?
A. So I've conducted my own literature search on -- I have done my own searches for oxidative degradation of polypropylene.
For the internal documents, we were provided with documents by the attorneys. We didn't have access to those through literature.
Q. Is it fair to understand, though, specifically for the Ethicon mesh, that you didn't conduct an internal -- strike that.
Is it fair to understand with respect to the Ethicon mesh that you didn't conduct a new literature search about the oxidative effects on polypropylene?
A. Not for specific Ethicon products. I was focusing more on the mechanisms of oxidative polypropylene in general.
Q. As a part of your work and your opinions in this case, did you ever focus on the mechanisms of oxidation of polypropylene for Ethicon products specifically?
A. Could you repeat that?
Q. Doctor, you testified -- strike that. Doctor, in the course of your work in this

Page 41

case, did you ever analyze the extent to which Ethicon mesh specifically degrades?
A. There was some internal documents that there were references in one of these is addressed in the rebuttal report. We just received a document.
There was a 1987 study. There was a human study and a study in dogs that were done by Ethicon that discussed oxidative degradation of polypropylene. These were with Prolene sutures, I believe, and not the mesh. It was the sutures.
Q. Other than the internal documents that you described, did you conduct any investigation to determine the mechanism of any oxidative degradation that Prolene mesh undergoes?
A. Not specific to Prolene. I think in some of the literature studies, Prolene or TVT Ethicon meshes were reviewed. But it's polypropylene, so we were focusing really on the oxidation of the polypropylene molecule.
Q. What did you do in formation of your opinions in this case to understand the history

Page 42

of Prolene?
A. I reviewed the documents that are in the reference materials.
Q. Do you know how long Prolene has been in the market?
A. I believe since the 1960s.
Q. Do you know the application for Prolene since the 1960s?
A. I know it's used in sutures and hernia mesh and in the pelvic floor meshes.
Q. Do you know how Prolene happened to be introduced as a medical device in the 1960s?
A. I don't remember the history of that.
Q. Are you familiar with a term known as a new drug application, NDA?
A. That's a regulatory term, I presume.
Q. What's your understanding of what a new drug application is?
A. I don't know that I'm familiar with the new drug application. My work is more in devices where we're dealing with PMAs and 510Ks. And a new drug application I'm not as familiar with.
Q. What's your general understanding of

Page 43

what that is, to the extent that you have one?
A. I would presume that when a company develops a new drug, they submit a new drug application. But that specific term, I don't know the details of it.
Q. In learning about the polypropylene used in Prolene, did you review any of the testing conducted by Ethicon since the 1960s in connection with the safety and efficacy of the polypropylene used in Prolene?
A. Primarily, the dog study and human study were the primary documents that I reviewed.
Q. And the dog study would be the seven-year dog study?
A. The seven-year dog study published in 1992.
Q. What was the human study you referred to?
A. I wouldn't call it a human study. It was sutures explanted from vascular grafts in human patients. That one was done in 1987.
Q. That must be in your rebuttal report?
A. It is.

Page 44

Q. I'll get it here in a minute. No problem.
Were those the only two studies you've looked at to understand specifically the testing done by Ethicon on the safety and efficacy of the polypropylene used in Prolene since its introduction in the '60s?
A. There was a 17-year study done by Nielson published about maybe 2011, I think, 2013.
Q. You've opened your book.
A. That's this one.
Q. You obviously have that in your notebook there?
A. Yes.
Q. I didn't see that referenced in your report. For what purpose did you look at the 17-year Nielson study?
A. Well, it was a long-term study on the TVT device, not the TVT-O but the TVT device.
Q. Do you understand that the mesh used in the Nielson study for the 17-year data that's contained in that study is the same mesh that's used in TVT-O?

Page 45

A. Yes.
Q. Are you able in your area of expertise to use the results from the Nielson study that you have in front of you? Can you transfer those to TVT-O?
MR. JACKSON: Object to the form.
A. There are differences in my understanding between TVT and TVT-O in the approach and the instruments.
The mesh is the same, is also polypropylene. But whether or not you can translate this to TVT-O, I don't know. I'm not a surgeon. But I know it's also polypropylene mesh.
Q. Of what significance to you is the Nielson study that you have in front of you, the 17-year data?
A. Well, it's not that many patients and they -- a fraction of them, they followed -- maybe 60 percent they followed out to 17 years. One of them had a complication, an erosion. But I think it's just another piece of data.
I mean, Dr. Nielson is -- I think it says in the back here that he's a consultant

Page 46

for Ethicon. So, you know, he has interest in success of the material. It's one study done by a clinician who is pretty connected to the material.

Q. Do the findings in the Nielson study, the 17-year data support your opinions in this case?

MR. JACKSON: Object to the form.

A. There was an erosion in one of the meshes that would be consistent with my opinion that polypropylene undergoes surface oxidation which leads to embrittlement, can lead to erosion and other types of complications.

Q. There's nothing in that study to suggest that there's degradation involved in the one erosion that's there, is there?

A. I don't think they looked at that.

Q. Is that the only point in the Nielson study upon which you rely to support your opinions, the fact that an erosion occurred?

A. There wasn't a lot of -- I mean, the examinations that these women received, some of them they talked to over the phone. It was a quality-of-life survey in older women. So to

Page 47

me, it's a bit difficult to interpret. Were there other types of complications? It's hard to say.

The data just aren't that -- they say in here that a lot of the patients didn't want these invasive evaluations. So it's very qualitative. It's difficult for me to take much away from it. It's just another piece of information.

Q. All I'm trying to understand is you've obviously pointed this out to me as something in your file that's of significance to you, and I need to know the significance of it to your opinions in the case.

A. So, I mean, I thought I answered it. There was one patient had an erosion. And it's difficult for me to rely heavily on this document just because of the types of data that was collected. It wasn't specific to the types of questions that we're asking. I would say it was more inconclusive, if that's what you're asking.

Q. Okay. So have we identified now the studies that you looked at specific to Ethicon

Page 48

mesh or suture in connection with your opinions in the case?

A. I believe so. Well, yeah, for specific -- yes, I believe so, for specific Ethicon products that I can remember.

Q. Right. Dr. Guelcher, have you ever used the term "gold standard"?

A. I think a lot of people use this term. It can apply to a lot of -- it depends on the context of what you mean.

Q. How do you use the term "gold standard" in your work?

A. I don't think I use it very much. It can be used in the context of almost like a clinical control. So in my work in bone grafting, a lot of people refer to autograft bone as the gold standard. It's the most successful approach for healing bone.

That doesn't necessarily mean it's preferred or the best way to do it. It's just what's known to be the most effective. So autograft bone has its deficiencies. People still refer to it as the gold standard because it's the best known approach basically.

Page 49

Q. And in the bone graft context, there's no perfect bone graft procedure; fair?

A. Well, the problem with autograft is that you have to get it from somewhere. That introduces a lot of limitations. And so there's a number of different approaches that can be used.

Q. At least that is -- the autograft bone procedure is known as the gold standard in your area of expertise because it's the best that you-all have available at this time; is that fair?

A. That's the way a lot of -- I think that's -- I mean, understanding within the field is that autograft is the gold standard in terms of healing.

Q. Have you made any investigation to determine the extent to which the use of polypropylene in tissue repair has been considered the gold standard since the '60s?

A. Well, I don't know that I would agree with that statement. I think some of Ethicon's own documents and e-mails say that they're moving toward these PVDF meshes because the

Page 50

inflammatory response is less severe.
Q. My question is very simple: Have you made any investigation to determine the extent to which polypropylene has been considered the gold standard in tissue repair since the 1960s?
A. Well, I think I just said other people may consider it the gold standard. I looked into these documents, and I don't consider it the gold standard. It's an unstable material in my opinion.
It may have been the best one available in 1960, but I think recent evidence points to the contrary that there are alternative materials available.
I think even Ethicon's own e-mails there are statements that we need to move to a different material because of problems with polypropylene.
Q. And what material -- do you have an opinion that there's a better material than polypropylene in the treatment of stress urinary incontinence?
A. That opinion really wasn't the subject of my report. I can say that in the

Page 51

documents that I reviewed, there were Ethicon employees and I believe even consultants pointing out that PVDF, for example -- there are some papers that have pointed out that PVDF would be a better choice, but I didn't look at that specifically in my report.
Q. Do you know what PVDF is?
A. Polyvinylidene fluoride.
Q. Have you ever studied the use of polyvinylidene fluoride in the context of tissue repair?
A. No. Like I said, that's outside the context of my report. I'm just noting that even Ethicon employees are doubting this notion that polypropylene is the only thing available.
Q. Do you know of any PVDF mesh available for sale in the United States?
A. No. It would require another regulatory filing.
Q. Now, at what point, to your knowledge, was PVDF available as an alternative?
A. I believe -- let me look at the document.

Page 52

Q. Are you referring to Ethicon documents now?
A. Yes.
Q. Are you looking at the seven-year dog study?
A. I am. So they were looking at alternatives. One of the alternatives was Ethylon, Novafil, Prolene, and they point out that -- let me look at this for a minute.
So in this dog study, some of the dogs were implanted with PTVF sutures in 1987, and I believe that -- so this report is basically saying PVF and Novafil did not show the surface cracks and surface oxidation that Prolene was showing. So this would be 1992, I think this was published. Yeah.
Q. Is it your understanding that the Ethicon dog study was published?
A. I mean published internally. It looks like it's an internal report to me. That's what I meant by published. Submitted, I should say.
Q. Doctor. Is there any significance to your opinions in this case, whether you are

Page 53

looking at Prolene that's sutured or Prolene in mesh, in terms of the oxidative degradation issues?
A. Well, there's a number of comments in the internal Ethicon documents about moving from heavy-weight to light-weight mesh, the notion being just having less polypropylene has been associated with a reduced inflammatory response.
Mesh is different than sutures. It's implanted in a different anatomic site where there could be differences in load-bearing. There could be differences in the cellular infiltrate. There's many types of differences.
So I don't know that -- you can learn some things from the suture studies, but it's not necessarily representative of how much degradation you would see in a mesh. I would think you would see more in a mesh.
Q. Why?
A. Because there's more polypropylene there. It's -- especially in the pelvic floor, it's bearing a load, so it's under a different types of stresses and strains. So the

Page 54

consequences of those, oxidative degradation could be different in a mesh than you would see in a suture.
Q. Are your opinions in this case specific to meshes?
A. Well, I think my opinions relate to oxidative degradation of polypropylene and then how that can affect the mesh. That's my --
Q. I understand that. But are your opinions in this case specific to meshes and not sutures?
A. Yes. I'm not here to testify about polypropylene sutures. I was looking at the suture studies because it was the data that was available to evaluate the body's response to polypropylene.
Q. And are your opinions in this case specific to the polypropylene mesh used for the treatment of stress urinary incontinence?
MR. JACKSON: I'm going to object to form.
A. So, again, my opinions are generally to oxidative degradation of polypropylene and how that can affect its performance in the SUI

Page 55

application.
Q. (By Mr. Thomas) You've not looked at the extent to which oxidative degradation of polypropylene can impact the performance of Prolene in other applications?
A. Like hernia or something?
Q. Correct.
A. That's not what I'm saying in the report or testifying to. It's the meshes and the SUI.
MR. JACKSON: We've been going for about a hour. Do you think it's time for a break?
MR. THOMAS: That's fine.
(A break was taken from 10:26 a.m. until 10:39 a.m.)
Q. (By Mr. Thomas) Doctor, I want to move to your report which we've marked as Exhibit No. 1.
A. Okay.
Q. Go to page 4 of your report, please. The second paragraph on page 4, you talk about -- you make the statement, Although polypropylene can never be considered inert.

Page 56

Is there any material that can be used for medical implants that can be considered inert?
A. Some are less active than others. I don't know if it's anything that's completely inert.
Q. You continue and say, It's often stabilized against the threat of oxidation by adding antioxidants to the molten polymer. These antioxidants are supposed to act as scavengers that will react with any oxidative species.
Do you know how, if at all, Ethicon stabilized Prolene against the threat of oxidation by adding antioxidants?
A. So there's some information in the internal documents I know they made some changes to stabilizer levels. The stabilizer levels that I saw were reported as ranges.
In the 1987 human explants, it was noted that the antioxidant was depleted in the surface oxidized layer on the polypropylene.
My understanding was the oxidants were added to protect against oxidation during thermal processing. But to dose an antioxidant

Page 57

over the lifetime of the device in vivo would be -- I don't know if that can be done. That's what I'm saying in this paragraph.
Q. What did Ethicon do to stabilize its polypropylene against oxidation?
A. In the human study -- not the human study. The human explanted materials, they were using --
Q. I need you to identify what you're reading now.
A. Oh, this is the report issued on human explants from human vascular graft, Prolene sutures removed from human vascular graft.
MR. JACKSON: Is there a Bates number at the bottom of that?
THE WITNESS: Ethicon mesh 12831391.
Q. (By Mr. Thomas) It's dated September 30, 1987?
A. Yes.
Q. And it's an Ethicon document?
A. Yes.
Q. It says, IR microscopy of explanted Prolene received from professor R. Guidoin?

Page 58

A. Yes.
Q. When did you first see those documents?
A. Yesterday, I believe.
Q. And how did you obtain those documents?
A. Dr. Dunn asked for this document, I believe. I got it from him. I believe he asked the attorneys for it.
Q. And what does --
A. You asked about the antioxidants.
Q. Correct.
A. I believe that this report -- I need to find it. Dilauryl thiodipropionate, DLTDP, is what I believed -- I believe they were using this as antioxidant in the suture at this time. It appears reduced in the two-year sample spectra and further reduced in the eight-year sample spectra. And in the material they scraped off the surface, they did not find any of it. That's what the report says.
Q. Okay. Just for the record, that's marked as document No. 18?
A. Yes.

Page 59

Q. In Exhibit No. 3; is that right?
A. Yes, that's right.
Q. And you received that document yesterday. Any other documents that you received yesterday that you rely on for your opinions in the case?
A. Well, they're in this notebook.
Q. This is the new binder?
A. Yes. So this was one that I brought with me. These are some --
Q. I see.
A. Most of this I got from Dr. Dunn. He had requested a number of these documents, and he got them from attorneys and we reviewed them yesterday.
Q. I see. So the documents in Exhibit No. 3 go with the rebuttal report that you were served yesterday?
A. They do, yeah.
MR. THOMAS: For the record, I'm going to mark as Exhibit No. 5 -- Exhibit No. 5 is an expert rebuttal report from Scott Guelcher, Ph.D., that I received for the first time this morning. And the

Page 60

documents -- I guess there are 20 documents in a notebook which we've marked earlier as Exhibit No. 3.
(Exhibit 5 was marked.)
Q. (By Mr. Thomas) Those 20 documents are the documents upon which you rely for the substance of your rebuttal report, Exhibit 5?
MR. JACKSON: Object to the form.
A. Well, the rebuttal report also includes the documents submitted. The rebuttal report also includes documents in the first report.
Q. Okay. But the new documents for the rebuttal report are contained in the notebook, Exhibit 3, that you brought here with you this morning?
MR. JACKSON: Object to the form.
A. I believe that they are.
Q. (By Mr. Thomas) Other than document No. 18 in Exhibit No. 3, do you have any other documents to support your opinion that the antioxidants used in the Prolene mesh were not sufficient to stabilize against the threat of oxidation?

Page 61

A. This is the only document that has the in vivo analysis of that.
Q. Okay. Going back to my original question, what did you do to understand how Ethicon used antioxidants to stabilize Prolene against the threat of oxidation?
A. So Dr. Dunn was looking at this more in his report. I discussed this topic with Dr. Dunn. He showed me some documents providing ranges of the antioxidant that were provided.
There were some changes made to the antioxidant levels as well. I'm not sure that we were able to identify what those were. But I do believe there were some documents stating that the antioxidant levels were changed, but Dr. Dunn was looking at that. I discussed it with him.
Q. Do you have an opinion that you're prepared to offer to a reasonable degree of scientific certainty that the antioxidant package used by Ethicon for Prolene is inadequate to protect against oxidation in vivo?

Page 62

A. My opinion is that the antioxidant used cannot protect against oxidation in vivo. I believe that because of the teachings of Jim Anderson that this chronic inflammatory response foreign body reaction is ongoing and will continue to oxidize material and deplete the antioxidant.

That observation is basically supported by these studies on the sutures from the human explants and, you know, consistent, I think, with the field that you simply can't protect a device over its lifetime. It's going to be implanted in a patient over the patient's lifetime with an antioxidant. Eventually, it will be depleted.

Q. Can you tell me today what the antioxidant package that Ethicon used to protect the Prolene polypropylene from oxidation was?

A. I don't know what it is today. In this report in 1987, it was DLTDP.

Q. Is that all it was?

A. That's what it says in this report.

Q. Have you tried to determine the

Page 63

specific antioxidant package Ethicon used to stabilize Prolene against the threat of oxidation?

A. Dr. Dunn and I looked at this. Like I said, our conclusion was that the documents provided a range of antioxidant. It didn't provide a specific dose.

Q. Can you tell me today as you sit here in this chair the antioxidant package Ethicon used to stabilize Prolene against the threat of oxidation?

A. I don't remember what it was.

Q. Is it your opinion, Doctor, that there is no antioxidant package available that can effectively stabilize polypropylene against the threat of oxidation?

A. I don't believe it's possible to stabilize an implant against oxidation over its entire lifetime. I don't know that there's much data on what the dosing should be. If it's dosed too high, that could cause problems. There's papers that have noted that.

The problem is it's an inherently unstable material, and stabilizing it is going

Page 64

to be very difficult. No matter what antioxidant is added, it's going to be gradually depleted over time.

Q. What's the basis for your opinion that whatever antioxidant is available is going to be depleted over time?

A. Well, the paper by Jim Anderson and other papers that have shown that this foreign body reaction is continuous and ongoing and it's going to continue as long as the material is there. Eventually, that antioxidant is going to be depleted.

I suppose you could put it in at very high doses, but then you're going to have toxicity concerns. To my knowledge, nobody has studied that, what's the amount of antioxidants to add to protect it over its lifetime.

Q. Is it your opinion that the antioxidant package Ethicon used is inadequate or that it can't be done?

A. Well, my opinion is that the antioxidant used in 1987 is inadequate. That opinion is supported by Ethicon's own data.

I don't know what -- I don't remember

Page 65

what the antioxidant is that's being used today, but my opinion would be that that would also be inadequate. Over time, it's just going to be depleted and you can't guarantee that it's going to stay there.

Q. Okay. And the same would be true for any polypropylene used as a medical device; fair?

MR. JACKSON: Objection to form.

A. I don't believe polypropylene can be stabilized effectively over its lifetime when implanted in a human or animal.

Q. (By Mr. Thomas) What's the risk when you're unable to stabilize the polypropylene used as a medical implant over the life of the implant?

MR. JACKSON: Object to the form.

A. Well, the risk is exactly what's pointed to in this Ethicon study. At two years, I don't believe they saw --

Q. This is Tab 18 again, the Guidoin study?

A. Yes. I need to review this again for just a minute. There are a lot of documents.

Page 66

So I can say that as you go from two to eight years, the amount of DLTP -- DLTDP was reduced, and in that surface oxidized layer it was gone.

So I think this study supports the idea that stabilizing polypropylene against in vivo degradation permanently for the lifetime of the patient is going to be very difficult. Eventually, the material will oxidize and become embrittled.

And those are the consequences, I believe, to not being stable.

Q. Okay. Are you aware of any study published in peer-reviewed literature which suggests that Ethicon Prolene loses its antioxidant package such that it oxidizes and becomes embrittled, as you've described it?

A. I'm not aware of a published study that's shown that. But, then again, Ethicon's internal study reported that.

Q. What have you done to understand the circumstances of the study that's in Tab 18 of Exhibit 3?

A. I've read the study, and then there

Page 67

were some minutes that were issued to schedule a meeting to -- I think at the meeting, they talked about the implications of the study where they were going to measure -- there was concern about how deep are these surface cracks. And I think Dr. Dunn was trying to find additional information, SCM. We couldn't find that information. So this was all we could get on this particular study.

But there was a follow-up meeting. We have some minutes from that, but we don't have much additional -- they measured some crack depths. But I believe it was the SCM images that we didn't have. We have FTIR data here for no SCM.

Q. Okay. Is it your opinion that the DLTDP is the only antioxidant in Prolene?

MR. JACKSON: Objection to form.

A. Well, I think I've already answered that. In 1987, this report refers to the DLTDP stabilizer antioxidant. I can't remember what's used today. I know there was a range of doses in the material. That range is pretty broad. But I don't remember what the current

Page 68

antioxidant is.

Q. (By Mr. Thomas) Do you know whether there's more than one in 1987?

A. In 1987, I don't know. This report just refers to DLTDP. That's -- it doesn't say whether there's another one. It just talks about DLTDP.

Q. Have you made any effort to understand how Ethicon arrived at the antioxidants that it uses to stabilize Prolene against the threat of oxidation?

MR. JACKSON: Object to the form.

A. Again, there were a limited number of references that we talked about. I believe reviewing some of those documents with Dr. Dunn, there was a change made in the antioxidant levels, and we were trying to find additional documents to explain that change, why it was made. And I don't believe that was successful.

Q. (By Mr. Thomas) Is Tab 18 in this document the extent of Exhibit 3, the extent of your knowledge of what you believe to be depletion of the antioxidants in Prolene?

Page 69

A. This is the only study that I'm aware of that we found that addressed the antioxidant question directly.

Q. In your review of documents in connection with this case, are you aware of any other documents that you've reviewed which address the depletion of antioxidants in Prolene suture or Prolene mesh?

A. This is the only one that we could find that directly addressed the antioxidant question, how much antioxidant is left.

Q. So if I'm going to ask you the question on what documents you rely to support your opinion that the antioxidants in Prolene suture are depleted over time, you would point to Tab 18 in Exhibit 3?

A. Well, there's indirect information in the dog study because the dog study observed surface cracking that would also be a consequence of oxidative degradation and embrittlement. But they didn't -- I don't believe in this study they actually looked at the amount of antioxidant remaining.

Q. Anything else?

Page 70

A. Those are the two studies that I'm aware of that looked specifically at this question.
Q. Let's go back to your report on page 4 again. In the middle of the second paragraph, it says, Nor is this stabilization permanent. The purpose of using antioxidants is to react with any oxidated species that threaten the molecular structure of the polypropylene chain. You cite to footnote 4, but there's no footnote 4.
A. I'm not sure what happened there. It must be an oversight.
Q. Do you recall the paper upon which you relied for that statement?
A. I don't recall the paper for that one. But I think the point of this statement is really in my experience, antioxidants are added to protect for a certain shelf life. So you would add an antioxidant to protect a polymer for a three-year shelf life.
These types of studies can be done in the known. That type of dosing can be done. What I'm saying is that trying to determine the

Page 71

dosing to protect against in vivo degradation is another question.
Q. Let me ask you this question: Is it your belief that the antioxidants that are added to Ethicon prolene polypropylene are merely for shelf life consideration?
A. There was a statement that I read in one of the documents. I can't remember which one it was. But there was an Ethicon document that made the statement that the stabilizer was added to protect against mechanical and thermal processing.
Q. Is it your opinion that the antioxidants added to Prolene polypropylene are only to extend the shelf life of that product?
A. The only evidence I have for the purpose of adding antioxidants was to stabilize it against manufacturing shelf life in the box before it's implanted. I didn't see any evidence in the documents that I reviewed where antioxidants were added dosed for the purposes of in vivo stability.
(Exhibit 6 was marked.)
Q. (By Mr. Thomas) A minute ago, you

Page 72

discussed the Anderson article. Let me hand you what I've marked as deposition Exhibit No. 6 and ask you if Exhibit No. 6 is the Anderson study to which you've cited in your paper.
A. Yes.
Q. And I believe I heard you say that you cite Anderson for the proposition that over the life of the material, that antioxidants will be depleted. Did I hear that correctly?
MR. JACKSON: Object to the form.
A. I think what I said was this foreign body reaction will continue as long as the material was present.
Q. (By Mr. Thomas) Okay. Does the Anderson article speak to the issue of the extent to which antioxidants added to polypropylene will be depleted over time?
A. Not directly. I was using Anderson to support the notion that the foreign body response is ongoing.
Q. Are there any of the studies that you've cited in your report, Exhibit No. 1, that support the proposition that antioxidants

Page 73

added to polypropylene deplete over time and create a risk of degradation?
A. As I said before, the only study that looked at specific questions of antioxidant loss would be the human explants from 1987.
Q. That's Tab 18 in Exhibit No. 3?
A. Yes.
(Exhibit 7 was marked.)
Q. (By Mr. Thomas) Let me show you what's been marked as deposition Exhibit No. 7. Deposition Exhibit No. 7 is a study, 1976, titled Subcutaneous Implants of Polypropylene Filaments, lead author Liebert. You cite this in your paper, don't you?
A. Yes.
Q. This is a 1976 study that compares polypropylene implanted in animals with antioxidants and without antioxidants; correct?
A. Yes.
Q. The Liebert study finds that the polypropylene treated with antioxidants does not degrade?
A. In this particular study in this implantation site for this period of time, they

Page 74

were able to protect it from degradation. Let me look -- I need to look at this for a minute.

So they went out to an implantation time of 160 days. I think that's five or six months.

So I'm not saying that you can't protect it for a period of time. I mean, even the human explants showed some antioxidant after eight years. I'm saying it's reduced. So this is five months. But if you go out years, these devices are made to be implanted in humans for their lifetime.

If you go out for very long periods of time, I don't think you can guarantee that these antioxidants -- they didn't even measure the anti -- I don't think they did. I would have to look at it again.

So I'm not saying that you can't protect it for some period of time. I'm just saying that I doubt whether you can protect it over the lifetime of the device on every patient, that you can protect it from oxidation. This is only five months.

At eight years in these sutures

Page 75

explanted from humans, they saw loss of antioxidant.

Q. When you talk about the sutures at eight years, again, you're talking about Tab 18 in Exhibit 3 of your rebuttal report?

A. Yes.

Q. So you would suggest that Tab 18 of Exhibit 3, the suture study, is inconsistent with the findings in Exhibit 7 in Liebert?

A. No. I think they're consistent. Liebert only went out five months. What this study is saying -- let me read the findings again.

Q. Just for your benefit, I don't have that study.

A. I understand.

Q. I'll get that, but I don't have that.

A. I understand that. But what this study is saying is -- I need to find it.

So the DLTDP appears reduced at two years. Two years is longer than five months. And at eight years, it's further reduced. And then in the oxidized material that they scraped off, they didn't find it.

Page 76

So I see this study as being consistent with Liebert. I think Liebert was asking a different question. I think Liebert was saying, Well, for five months, I can add enough antioxidant to stabilize the polypropylene. So I want to compare stabilized polypropylene -- it's like a control -- versus unstabilized polypropylene.

So Liebert was going after a different question, but he just didn't go out as far as this study did. So I don't really see any consistencies between these two studies.

Q. Are you aware of any studies in the peer-reviewed literature that support your position that stabilizers used to protect against oxidation in polypropylene deplete over time and create a risk of the oxidative degradation of polypropylene?

A. There's no studies that have specifically shown that. But I think from what we know about the foreign body response, that the oxidative attack is continuous and ongoing.

What we know from the human explants,

Page 77

initially that antioxidant is going to be depleted. That's what I think we know.

Q. We know from your earlier testimony that polypropylene has been used in tissue repair for 50 years now; correct?

A. Yes.

Q. Wouldn't you expect that to be an issue of significance in the medical and scientific literature if polypropylene used for the last 15 years loses antioxidants and poses a risk to the patients?

A. I don't know if -- the papers I'm actually familiar with that I reviewed are not specifically looking at the question of antioxidant depletion, but they do show signs of oxidation.

So if there's signs of oxidation, this study confirms it. And you would anticipate that if it's oxidizing, the antioxidant is not protecting it.

Q. That's something that could be tested, though, couldn't it?

A. Well, they tested it here.

Q. You're talking about the Ethicon --

Page 78

A. In the human explants, yeah.
Q. I'm talking about in the peer-reviewed literature to the extent that was a phenomenon going on, that was something that could be presented in a controlled scientific test that could be subject to peer-review and published in the literature?
A. They should be able to do that. That's just not what those studies did. They were looking more at signs of surface oxidation like Liebert did. They were looking at the phenomenon of surface oxidation.
Q. The Anderson paper that we just discussed, the Anderson paper you've cited for the proposition of the continuous foreign body reaction to the life of the explant; is that fair?
A. Yes.
Q. Any other purpose?
A. General background on the nature of the inflammatory response that was in the report.
Q. Dr. Guelcher, your education is what?
A. So I have a bachelor's degree and

Page 79

master's degree and Ph.D. in chemical engineering.
Q. And you've not studied polypropylene before your work in this case; correct?
A. No. But I've studied oxidative degradation of other polymers.
Q. And polyurethane is an issue of your interest?
A. Yes.
Q. Does polyurethane degrade in vivo?
A. Polyurethane is a broad term. So part of my research, we design lysine-derived polyurethane grafts that we published a couple of papers reporting that they undergo oxidative degradation. But those polymers are the tissue grafts, so they're designed to degrade oxidatively.
The other side would be biostable polyurethane implants. They are designed to be be biostable. Jim Anderson did a lot of work over the years investigating the oxidative degradation of polyether urethanes. So other materials such as polycarbonate urethanes have have been studied that are more exidatively

Page 80

stable. But the polyethers are known to undergo oxidative degradation.
Q. Is there any material of which you're aware that you could use for a medical device implant that is not subject to oxidative degradation?
A. Every material is going to -- the foreign body response is going to happen when you implant a foreign material. So the difference is materials -- materials respond differently to that foreign body reaction. And I think Ethicon's data points to polymers like PVDF as being more resistant to oxidative degradation. So some are more resistant than others.
Q. Are you saying that PVDF does not degrade by oxidation in vivo?
A. What I'm saying is, in the dog study, the PVDF sutures didn't show evidence of surface cracking. Now, whether there's oxidative degradation, you would have to use more sensitive techniques like XPS to actually characterize a surface.
At seven years in this dog study,

Page 81

they were not seeing the same amount of cracking that they saw in the polypropylene.
Q. Do you have an opinion, Dr. Guelcher, that there's any polymer that can be implanted in the human body that is not subject to oxidative degradation?
A. That's not really within the scope of my report. I mean, my report is focusing on oxidative degradation of polypropylene. I'm just noting observations that there are polymers that appear to undergo less oxidative degradation.
Q. Whether it's in the scope of your report or not, do you have an opinion in that regard?
A. I have an opinion that some materials are going to degrade more slowly in response to that foreign body reaction than others. But I don't know that it's been shown conclusively that they do or don't. The data aren't there.
Q. So is it fair to understand that you do not have an opinion as to whether there's any polymer that's available for implantation as a medical device that does not undergo

Page 82

oxidative degradation?
A. I mean, I wouldn't say does not. I would just say it's much more stable than polypropylene. There are polymers that are more oxidatively stable than polypropylene.
Q. What are those?
A. Well, the PVDF and --
Q. What else? We've talked about PVDF. Anything else?
A. What else did I look at? I said polycarbonate urethanes are more stable against oxidative degradation than polyethers. Those would be a few.
Again, I'm not -- I'm focusing in my report my opinions on that polypropylene degrades oxidatively in a significant rate.
Q. Going back to your report, page 4, note 4, do you know what site is appropriate there that is left out in footnote 4?
A. I don't. I don't have that with me.
Q. The next paragraph says, The oxidation of the polymer on the tertiary hydrogen bond is the rate controlling step in this process, and it will result in the

Page 83

polypropylene's molecular chain being broken and the reaction repeating until no more polypropylene can be broken down. What does that mean?
A. I think that statement is referring to this autocatalytic effect. Once you start to form these reactive species on the surface, it just continues to react. There's no reason for it to stop. It will continue to react and in later stages of degradation, there could be molecular weight loss and embrittlement.
Q. At what stage would there be molecular weight loss?
A. That's addressed by this concept of the induction time. So the paper by Fayolle and Liebert, these papers together are suggesting -- there's a -- Fayolle put out the notion that embrittlement can happen -- this is in figure 1.
So the induction time that's measured by, in this case, the FTIR measurements, the induction time is where there's this sharp change in the slope of the curve. So the concentration of hydroxyle and carbonyl groups

Page 84

is relatively -- it's a very small slope.
And then at some point when that induction time is reached, it becomes autocatalytic, and the concentration of those groups increases.
What Fayolle is saying is that critical molecular weight for embrittlement in the materials he looked at, he was reporting a molecular weight of 200,000 grams per mole. And he noted that that embrittlement on the basis of mechanical testing, that embrittlement is happening prior to the induction time measured by spectroscopy.
Q. I'm going to need you to help me understand these charts.
A. Okay.
Q. We're on page 5 now of Exhibit No. 1.
A. Right.
Q. And these are charts that you borrowed from Dr. Fayolle's paper?
A. They were published in the Fayolle study from 2000.
Q. At the top of (a), it says spectrophotometric induction time. What does

Page 85

that mean?
A. The spectrophotometric induction time is the time at which there's that change in the slope of concentration of hydroxyle groups and carbonyl groups. So that line is almost flat, so there's very small change.
And then at some point, it becomes autocatalytic. The concentration of these groups on the surface is high enough that now the rate at which the oxidation reaction is happening is much faster. That's the induction time.
Q. Just for my benefit, the spectrophotometric induction time is represented in figure A as the triangles and squares at the bottom?
A. Yes.
Q. And so at the point at about, oh, 250 to 260 is where there's a change in the hydroxyle groups and carbonyl groups which reflects a chemical change in the polypropylene?
A. That's right.
Q. So the embrittlement induction time

Page 86

means what?
A. This is a nice part of the work that Fayolle did. He was measuring ultimate elongation here by this. So embrittlement induction time, that's where the axis on the left with the curves with the hash lines, as you can see, the elongation is relatively constant. Then when you reach this embrittlement induction time, the material becomes highly brittle and less elongation.
Q. What does elongation mean?
A. That's the amount that you can stretch it. Out here, it's 800 percent. You can stretch it to eight times its initial length. When it becomes brittle, that number drops below -- then even small amounts of strain cause the material to fail.
Q. Now, is it fair to understand -- again, me trying to understand this chart -- that at the beginning of the study, the range of the elongation is around 750 to 900?
A. Right.
Q. And then over time, it decreases and then drops off rather dramatically at about 125

Page 87

to 175 hours. Am I reading that correctly?
A. Yes.
Q. So after that period of time, you have a reduction in elongation and increase in embrittlement. And then about 75 hours later, you have an increase in the hydroxyle and the carbonyl groups. Is that fair?
A. That's right.
Q. Each one of these changes that are shown in Exhibit A amount to a change in the chemical structure of the polypropylene; correct?
A. Well, the hydroxyle and carbonyl groups, that's the introduction of bound oxygen. The embrittlement is a mechanical property. That's not a -- the structure of the polymer is changing. It's becoming brittle.
Q. But the chemical structure of the polymer does not change in figure A until you get to the formation of the hydroxyle groups and the carbonyl groups?
A. The chemical structure is breaking, and Fayolle explains the details. And there's some explanations for what could be happening

Page 88

there.
These concepts of tie chains and amorphous chains that connect crystalline regions are breaking and that can lead to embrittlement. So what Fayolle is saying is that changes in the polymer that lead to embrittlement happen before large concentrations of hydroxyle and carbonyl groups, which has been the traditional way. Even XPS would measure formation of hydroxyle and carbonyl groups on the surface.
What Fayolle is saying is that embrittlement happens you can really -- before that becomes appreciable. It becomes this autocatalytic increase.
Q. Now, figure B uses axes of molecular weight, time, and concentration moles per kilogram; correct?
A. Yes.
Q. Is B appropriate to overlay on A?
A. So my comments, my notations, on Panel B were designed to kind of interpret A especially in light of Liebert.
So Fayolle reports a critical

Page 89

molecular weight for embrittlement in the polymers he was looking at 200,000 grams per mole. The polypropylene samples he was using became embrittled when the molecular weight dropped to 200,000 grams per mole. That's what that critical molecular weight -- that's what Fayolle was saying.
Q. It starts at about 225,000?
A. That's when the material becomes sufficiently brittle that it's -- the material is basically brittle.
Q. This shows the change in molecular weight over time?
A. Yes.
Q. And at about 210 hours is when you reach a reduction in molecular weight from about 260 to about 200,000?
A. That's how Fayolle defined it, as embrittlement at that 200,000 molecular weight.
Q. The molecular weight then continues to become reduced until at about 260 hours the molecular weight of the polypropylene or whatever substance you're measuring at that point is down around 75,000; correct?

Page 90

A. That's right.
Q. Now, the hydroxyle group and the carbonyl groups are the same graphs that are on figure A; correct?
A. Yes.
Q. So at the bottom where you have time and days and subcutaneous implantation, what does that mean?
A. So I added the line -- the red line at the bottom is a way to interpret the data from Liebert. So what Liebert was teaching was that -- he reported an induction time of 108 days by his own -- he did very similar measures on explanted materials of hydroxyl and carbonyl groups.
And he reported in vivo induction time of 108 days. And then he notes if you consider molecular oxygen as the source and physiological temperatures, there should be an induction time of 20 years, and yet we're measuring 108 days. Clearly, there has to be some sort of reactive oxygen within the body.
Based on the work of Anderson and others, we know now that that's associated with

Page 91

the foreign body response. That's where the 208 days come from. That's the induction time measured by Liebert for unstabilized polypropylene explanted from the sutures in the films -- explanted from the hamsters.
So the 90 days is an approximation of this concept of Fayolle that it basically becomes embrittled before this induction time, and he's basically saying -- you can deduce from this as around 90 or a hundred days it's becoming embrittled, unstabilized polypropylene in vivo. That's what this is saying.
Q. And figure A is all Fayolle; correct?
A. Both of those plots, the plots themselves came from Fayolle. Everything in black came from Fayolle.
Q. All I have is black and white.
A. All right. So I used a different font. You can probably tell a difference in the fonts that I used.
Q. The time (days) subcutaneous implantation, where does that come from?
A. That is the time scale that Liebert measured. So what this plot is trying to do is

Page 92

pull together the auto-oxidation that's observed in air at elevated temperatures with what happens in the body. It's just a different source of oxygen, reactive oxygen in the body.
Q. So in the Fayolle part of figure B on page 5 where it shows at 210 hours there's the critical molecular weight for embrittlement, you drop down and get at about 90 days. How do those two -- 210 hours, which is less than ten days, and 90 days -- how can you draw those together?
A. Well, that's what I was saying. So the hours axis is that's the auto-oxidation that just happens with molecular oxygen as an oxygen source at elevated temperatures.
What Liebert is saying is this process happens over this time of about 100 days in vivo because there's a different source of reactive oxygen. It's the reactive oxygen species secreted by the inflammatory cells. That's why -- that's the difference in the time scale.
Q. Okay. And so the time scale for

Page 93

Liebert, where you say that the embrittlement will occur at about 90 days, is based upon Liebert's study of polypropylene without antioxidants?
A. Right.
Q. And the Fayolle study is based upon testing of polypropylene with the antioxidants removed; correct?
A. Let me look at the Fayolle study again to make sure.
Q. Do you recall that without looking?
A. Let me look at it for a minute.
Q. I have it for you here if that's easier.
A. I've got it.
MR. THOMAS: Let me mark it anyway as a deposition exhibit. It's deposition Exhibit 8, a copy of the Fayolle study.
(Exhibit 8 was marked.)
Q. (By Mr. Thomas) Exhibit 8 is a study titled Oxidation Induced Embrittlement in Polypropylene, a tensile testing study June 2000 by B. Fayolle, F-a-y-o-l-l-e.
A. So he says in the experimental

Page 94

section, The additives, I'm presuming the stabilizers, antioxidants were extracted in a soxhlet extractor in chloroform hexane ethanol. I would interpret that statement as saying that there was also unstabilized polypropylene.
Q. Have you seen any testing of stabilized polypropylene to support the positions that you take on page 5 of Exhibit No. 1?
A. No. These data were the data that I had for unstabilized polypropylene.
Q. Let's take a quick break please.
(A break was taken from 11:31 a.m. to 11:41 a.m.)
Q. (By Mr. Thomas) Let's go back to page 5 of Exhibit No. 1. Is it fair to understand, based upon your analysis of Liebert and Fayolle as depicted in these two graphs on page 5, that there is no embrittlement without a loss of molecular weight?
A. I don't know that I would say it that way. I would say that loss in molecular weight leads to embrittlement.
Q. Okay. The tests that we've just

Page 95

discussed -- strike that. The papers that we've just discussed by Fayolle and Liebert where you used test data from polypropylene without antioxidants, these same tests could be used for testing polypropylene with antioxidants, couldn't they?
A. These tests?
Q. Yes.
A. Yes. You have to go out to longer time points, but they could be used.
Q. Right. And to your knowledge, none of that testing has been done?
A. Not using this specific approach. I mean, there are papers where people have looked at explants and noted evidence of surface oxidation, but not this type of time course. A mechanistic study that would have to be done in vitro.
Q. The studies that you're referring to are the Clave and Costello articles that you referred to elsewhere in your report?
A. Yes.
Q. But in terms of the types of studies conducted by Liebert and by Fayolle that are

Page 96

discussed on page 5 of your report, to your knowledge, this type of analysis has not been done for polypropylene with antioxidant packages?
MR. JACKSON: Objection to form.
A. I don't know that this particular test has been done for polypropylene with the antioxidant.
Q. Okay. Now, the Fayolle paper, Exhibit No. 8, also deals with thermal oxidation of polypropylene films. Do you see that?
A. Yes.
Q. Does the fact that they're testing polypropylene films as opposed to polypropylene sutures or mesh have any impact on your opinions?
A. Let me look at this for just a minute.
I'm just looking to see if he -- they don't report film thicknesses.
Q. Look at the very beginning in the abstract. They talk about a hundred microns. Is that the thickness of the film?

Page 97

A. Okay. Yeah. I see a hundred microns. For some reason it's not in the experimental.
So my -- why I believe they used hundred micron films is because these films are very thin. So because they're so thin, these changes in the surface are going to result in molecular weight degradation because the sutures are much thicker. So -- they're on the millimeter scale.
Basically, because they're using these thin films, that allows them to measure these changes in molecular weight more accurately, because molecular weight is a volume average property. So if you use a very thin film, then surface degradation is going to contribute more to molecular weight loss of the bulk polymer.
Q. How big are sutures, did you say?
A. Three or five -- let me just look. It was in one of these studies. Let me find it. I thought it was. I can't seem to find it.
Q. It's not really important to my

Page 98

question.
A. Okay.
Q. Is there a difference between the use of a film and the use of a suture for purposes of this analysis done by Fayolle?
A. You would see the same changes on the surface of a suture that you would see on the surface of a film. But you might not see the same changes in molecular weight because with the film, the surface is a larger -- well, okay.
Q. The oxidation that Fayolle studies is thermal oxidation, isn't it?
A. It's thermal oxidation. That was the point of figure 1 in my report of page 5 was to connect the time scales. What Liebert was saying is thermal oxidation under physiological conditions, molecular oxygen, 37 c. would take 20 years, but he observes 108 days. That points to a much more reactive source of oxygen in the body.
So they're similar processes. It's just the difference in the source of the oxygen. Fayolle was looking at sort of

Page 99

thermally-induced where you heat it up, and molecular oxygen is actually the source of oxygen that causes reaction.
Q. Thermal oxidation, is at 90 degrees c.?
A. I don't know what temperature he used.
Q. First page of the abstract.
A. 90 c.
Q. And normal body temperature is 37 c.?
A. Yeah. But I was saying that Liebert noted that thermal oxidation in the body is much slower, but there's another source of reactive oxygen. That's the reactive oxygen secreted by the inflammatory cells in the body.
The purpose of that figure was to show that -- Liebert has a similar plot of hydroxyl and carbonyl groups from the explants. It's the same reaction. It's just a different source of reactive oxygen.
Q. So the conclusions that you reached with respect to opinion No. 1 in your report are based upon your review of the literature that you've discussed and not on any testing

Page 100

that you conducted yourself; true?
A. Yes. These are literature data. As I said earlier, we didn't even have materials to test for this sort of work.
Q. Paragraph 2 on page 6 titled Polypropylene Degradation In Vivo, the second full paragraph says, Macrophages and FBGCs attached to biomaterials are known to lead to degradation and device failure.
There's no cite there. Do you know what cite is appropriate there?
A. Which paragraph is this again?
Q. Right in the middle of the page, adhesion of macrophages. The last sentence reads, Macrophages and FBGCs attached to biomaterials are known to lead to degradation and device failure?
A. I believe Anderson discusses this point. In my own research, we've shown that macrophages attached to the scaffolds lead to active degradation. We published that in 2011.
Q. With what material?
A. With the polyurethane.
Q. Have you found any kind of literature

Page 101

which supports the proposition that macrophages and FBGCs attached to polypropylene are known to lead to degradation and device failure?
A. Well, some of the clinical studies report the presence of an inflammatory infiltrate in these cells, and some of these materials extruded or became affected.
Q. My question is simpler than that. My question is whether you're aware of any peer-reviewed literature which finds that macrophages and FBGCs attached to polypropylene are known to lead to degradation and device failure?
A. For polypropylene, it's not been studied specifically. But, again, in those images, it shows -- the ones that are more where you see these inflammatory cells, it's associated with oxidative degradation.
Q. Just so we're clear, though, you've not found any peer-reviewed literature that finds that macrophages and FBGCs attached to polypropylene lead to device failure?
A. I mean, that's a very narrowly worded statement. I don't want to be boxed in by

Page 102

that.
Q. Is it true?
A. I'm going to stick by my answer. There are inflammatory cells present, and he's explaining samples that failed.
Q. Is there any report in the peer-reviewed literature that any polypropylene mesh or suture failed due to macrophages and FBGCs attaching to polypropylene?
A. Let me look at Clave again.
(Exhibit 9 was marked.)
Q. (By Mr. Thomas) For the record, you're referring to Exhibit No. 9, which is the Clave article. So Clave reports two types of responses, a Type 1 and a Type 2 reaction characteristic of an infection. A majority of altered polymorphonuclear neutrophils were found; suggested an infectious process. This is on page 263 under the histological analysis.
He also reports a Type 2 reaction is chronic inflammation rich in giant cells and mononuclear cells. And then he also sees these -- evidence of what could be oxidative

Page 103

degradation. He sees evidence of cracking.
These are basically supporting his conclusions that these polypropylene implants are altered in vivo.
Q. * But there's nothing in Clave's article, Exhibit No. 9, that discusses device failure, is there?
A. Let me read what he wrote again. Well, I mean, these are a hundred implants, explanted from patients due to complications. So I would say that the device failed if they had to take it out because of complications.
Q. When you're talking about degradation, you're talking about the polypropylene being degraded to the point where it breaks or fails; correct?
A. No. I think that's discussed in my report, is where you have surface oxidation that can lead to molecular weight loss, embrittlement, cracking, is a whole chain of events that happens.
What I'm saying is that Clave took a hundred explants from patients that had complications that had problems with the mesh.

Page 104

And many of those explants, he saw inflammatory reactions associated with infection or a chronic inflammatory response.
He saw cracking on the surface which is consistent with oxidative degradation as even pointed out in Ethicon's studies, the dog study and the human explants.
He sees evidence by FTIR of carbonyl groups that are associated with oxidative degradation. Now he comments that he can't say whether it's oxidative degradation or whether it's something else, but it's consistent with the notion of oxidative degradation.
So when you take Clave plus Ethicon's own data that oxidation can lead to surface cracking and embrittlement, I think Clave is teaching that meshes that were explanted because of complications because they failed showed this inflammatory response and surface oxidation. That's the way that I would answer your question.
Q. Is Clave the only support that you have that macrophages and FBGCs attached to biomaterials are known to lead to degradation

Page 105

and device failure?
A. Let me look at Costello as well.
Q. Is Costello the only other one that you would look to? That's not an Ethicon mesh, by the way, is it?
A. No. But it does have a polypropylene component, I believe.
Q. Does it have a polypropylene component with the Ethicon added effect?
A. I don't know. Let me just see what he says. Yeah, these were the Bard composites. But he discusses oxidation. He has some SCM images showing surface effects, effects of surface oxidation.
Q. You're in the Costello study now?
A. Yes.
Q. Is polypropylene ever appropriate to use in a medical device?
MR. JACKSON: Objection to form.
A. I'm not really here to speak to that. I was looking at suitability for polypropylene in these pelvic floor-type applications.
Q. (By Mr. Thomas) For the pelvic floor, is polypropylene ever appropriate to use

Page 106

in a medical device?
A. Not saying whether it's appropriate to use or not. I'm saying that it can undergo surface oxidation due to the foreign body reaction that can lead to changes in the polypropylene, and those changes are not fully understood.
They're observed by Ethicon in their own studies. They were never really followed up on or understood. And so the long-term behavior of the device is unpredictable. I'm not saying that it can never be used. I'm saying because of these changes due to foreign body reaction, its performance can be unpredictable.
Q. You say it's unpredictable. Does that mean you do not have an opinion as to what will happen to the device over the life of its implantation?
A. I believe that over the life of its implantation, the polymer will change in response to the foreign body reaction. Well, specific changes would be loss of molecular weight, embrittlement. In some patients, that

Page 107

can lead to extrusion, pain. It's consistent with those adverse events in patients.
And I believe that the instability of the polymer can contribute to those adverse events.
Q. Okay. What is it that allows you to offer the opinion that the surface oxidation of polypropylene that you've described leads to extrusions?
A. Well, I think Ethicon even noted in some of their documents the importance of matching the properties of the mesh to the properties of the host tissue. This is known, it's true just -- it's important to match the properties of the implant to that of the tissue.
So if you have an implant that now is becoming very brittle, it's no longer comparable to the tissue that it's surrounded by.
Q. Is this something you're just deducing and piecing together or something that's based upon any kind of medicine or science?

Page 108

A. Well, I think that these papers are showing there is surface oxidation that we know leads to embrittlement. Then these devices that are extruded are infected as a complication.
So I think that these papers are showing the connection between the two.
Q. Are there any papers in the medical or scientific literature that suggest that surface oxidation of polypropylene mesh can lead to extrusion?
A. I think Clave is suggesting this, as I was explaining. He sees these hundred meshes where there were problems. He sees evidence of surface oxidation. He sees inflammatory cells and the infiltrate infection.
Q. Is that the sole basis for your opinion that surface oxidation of polypropylene mesh can lead to extrusions, the Clave article?
A. Clave would probably be the one.
Q. Anything about your own work that you've done in your training, education, and experience outside of Clave that leads you to conclude that surface oxidation of polypropylene mesh can lead to extrusion?

Page 109

A. Not that I'm aware of.
Q. What is the basis for your opinion that surface oxidation on polypropylene mesh leads to pain?
A. I think if you have a brittle piece of plastic embedded in soft tissue, it's going to be painful.
Q. Is this based upon what you know or based upon any scientific literature to support your position?
A. I would have to look for some papers on this. But, I mean, I think it's obvious if you have brittle plastic in your body, it's going to hurt.
Q. It's based on that obviousness as opposed to your review of any scientific literature; is that fair?
A. I can't think of a paper right now that explicitly says that.
Q. Just so we understand, you don't know whether the mesh in Ms. Edwards was brittle, do you, to use the term as you've used it?
MS. LEWIS: Objection: Form.
A. We didn't have an opportunity to

Page 110

measure that.
Q. (By Mr. Thomas) The same is true with the mesh of Ms. Edwards, you don't have any idea whether the mesh in Ms. Edwards was brittle, using the term as you've used it?
MS. LEWIS: Objection: Form.
MR. JACKSON: I'm going to object too. You brought two names in there.
MR. THOMAS: Let me start over again. I want to get a clean question.
Q. (By Mr. Thomas) It's fair to understand, Dr. Guelcher, that you don't know whether the mesh in Ms. Huskey was brittle using the term as you've used it here today.
MR. JACKSON: Object to the form.
A. Without the explant materials, we couldn't do that assessment.
Q. It's fair to understand that you don't know as you sit here today whether the mesh in Ms. Edwards was brittle using that term as you've used it here today?
MS. LEWIS: Objection: Form.
A. Without the explants, we can't do the measurement.

Page 111

Q. (By Mr. Thomas) On page 6 of your report, you again identify examples of polyurethanes which have degraded over time. Did you try to identify any polypropylene products that had degraded over time that led to device failures?
A. Well, I mean, again, I think Clave addresses this point of connecting surface degradation with failure of a mesh.
Q. Okay. Other than Clave, did you find any other evidence of device failure using polypropylene?
MR. JACKSON: Object to the form.
A. That's the one I can think of right now.
Q. (By Mr. Thomas) Okay. What is toughness?
MR. JACKSON: Object to the form.
A. Well, toughness is typically associated with the area under the stress/strain curve.
Q. What does it mean?
A. It's a measure of how much energy a material can absorb before it fails. So a

Page 112

brittle material would not be very tough because if you take it out to small strains, it fails.
Q. Okay. Do you know whether Ethicon Prolene after implantation is more or less tough after seven years?
MR. JACKSON: Object to the form.
A. Well, I think that question is rather complicated. Let me find the data.
Q. (By Mr. Thomas) Are you looking in the seven-year dog study now?
A. Yes. I'm trying to find the data. I don't know. I'm not finding the data here.
Q. Do you have a recollection of looking at the toughness data in the Ethicon studies?
A. From what I remember, there was the elongation was either the same after a year or even got a little worse after two years. And all of a sudden in seven years, it becomes much more ductile.
So I had questions about the methodology used to do those measurements. All the materials that were tested showed that same trend. All four of them, the Ethilon, Novafil,

Page 113

Prolene, they all showed that same trend.
So this report in the expert report focused on seven-year data. But if this were really going on, why aren't you seeing it in the one- or two-year data. It just seems strange to me.
Q. Have you seen other studies conducted on Ethicon prolene polypropylene analyzing the extent to which the implanted polypropylene is more tough than the pristine polypropylene.
A. The only data I've seen on Ethicon polypropylene is the dog study where they did mechanical testing on the sutures.
Q. And increased toughness and increased embrittlement are polar opposites of each other; is that fair?
A. Yeah.
Q. And if something became more tough, by definition, it becomes less brittle?
A. But that's if you believe those seven-year data. They seem flawed to me. The methodology in the report is not -- there's not a lot of details, and something seems wrong.
I don't understand why you can see

Page 114

this elongation, this increase in ductility in seven years and one and two years you're not seeing it.
Q. You've not conducted your own tests to determine whether these polypropylene sutures become more tough after implantation, have you?
A. No.
Q. On page 6 of Exhibit No. 1 in your report, you're talking about failure mechanisms that you've observed in connection with polyether urethanes and polyester urethanes. Do you see that?
A. Yes.
Q. Is this work that you've been involved in?
A. So the environmental stress cracking of biostable polyether urethanes is primarily the work of Dr. Anderson.
Q. Have you done any work in that regard?
A. We've done -- in the papers I've published, we've shown that these materials degrade in vitro -- they degrade in vivo due to

Page 115

oxidative degradation, and they degrade in vitro using a macrophage pocket simulating fluid developed by Dr. Anderson. We see a connection between those rates of degradation in vitro and in vivo that led us to conclude they're degrading by oxidation.
Q. Is the mechanism of oxidation that you've observed in the polyurethanes the same as the mechanism that you've suggested occurs with polypropylene?
MR. JACKSON: Object to the form.
A. The difference between the two polymers would be where the oxidative attack takes place in the chain. So in the polypropylene, it's the hydrogen on the tertiary carbon that's being -- that hydrogen-carbon bond is being attacked.
Q. (By Mr. Thomas) So the polyether urethanes would undergo environmental stress cracking, and then you would have subsequent loss of molecular weight?
A. The idea is similar to what we saw in the SCM images of the cracked polypropylene. Once the surface starts to crack, that

Page 116

generates new surface that oxidated species can use and cells can migrate into and continue this process of oxidative degradation. That's what that's referring to.
Q. When you look at, under scan electronic microscopy, environmental stress cracking of these polyurethanes, what do you see?
A. You see cracks in the material. I don't know what you mean.
Q. Does it flake off? Does it break? Does it propagate throughout the center of the fiber?
MR. JACKSON: Objection to form.
A. It can. They're not typically fibers. These are more bulk material.
Yeah, pacemaker lead insulation. So it's a different form of the material. It's not necessarily a fiber.
Q. (By Mr. Thomas) When you have oxidative degradation in the surface of the polyurethane in what you mentioned on page 6 of your report, does the material flake off?
A. It can. I don't know that it always

Page 117

does. That can be an outcome. Particulates.
Q. Does it crack down through the entire body of the implant?
MR. JACKSON: Object to the form.
A. I don't know if it goes through the entire body. The surface cracks, and then the cracks can grow.
Q. (By Mr. Thomas) Does the material flake off and cleave off so that you have a smooth surface underneath?
A. I don't know. I mean -- what I'm saying here is that it cracks, and then the cracks generate new surface that can lead to more oxidation. If pieces become embrittled, it can slough off like they saw in the dog study or the human explants where you end up with the layer of degraded material.
Q. What is crack propagation?
A. If the crack grows.
Q. It's like when you put a crack in a windshield and you press on it, it spreads across the windshield? That's crack propagation?
MR. JACKSON: Object to the form.

Page 118

A. I think that's a little different. I think crack propagation would be the crack into the surface can deepen. It can widen. Again, once it cracks, there's two things that can happen. It becomes mechanically compromised, and then it generates new surface for oxidative attacks. So the crack can grow and propagate through the material.

Q. (By Mr. Thomas) In what direction does the crack propagate? Does it matter?

A. You know, I would think it would be inclined to propagate in the direction of the stress. But it just depends on the loading, on the type of material.

Q. Something that could be tested, of course?

A. I think Ethicon looked at this too.

Q. I'm talking about you now, whether you could test --

A. I haven't done these studies. These are published studies. The materials that I work with are designed to be resorbable, so they don't typically crack. They're resorbed and replaced with new tissues.

Page 119

I haven't actually done experiments of measuring crack propagation.

Q. So you don't know how crack propagation would manifest itself in polypropylene which had undergone surface oxidation?

MR. JACKSON: Object to the form.

Q. (By Mr. Thomas) Is that fair?

A. Let me look at this document for a minute.

Q. What are you looking at now?

A. This would be a memo on crack depth in explanted prolene polypropylene sutures.

Q. This is another document that you've brought here today, Tab 19 in Exhibit No. 3 dated June 15, 1982?

A. Yes. So in this study, they were measuring the depth of the crack. They concluded that the sutures had crack depths varying from .5 to 2 microns. The diameter of the suture in this case was 25 microns.

Crack depth does not vary systematically with implantation time. It varies significantly from point to point along

Page 120

the fiber length. So they report measurements of crack depth. But there's no pictures. They just report the numbers.

These were materials that were implanted anywhere from two to seven and a half years.

Q. Is that the only information that you have to look to to determine the extent to which cracks will propagate in polypropylene?

A. Let me look at the other one, the human explants.

Q. That's Tab 18 in Exhibit 3?

A. Yeah. So, again, they don't provide a lot of details. This is one of the documents Dr. Dunn was trying to get. We don't have SEM images. They have microscopy observations by -- I think this is Mr. Schiller who did SEM.

At two years, he notes no cracking. At eight years, he notes severe cracking. Without the pictures, we don't know what that means. But he basically says that at eight years, they're severely cracked.

So these are the two documents that I'm aware of where Ethicon was looking at

Page 121

cracking of polypropylene sutures.

Q. My question, Doctor, are those two documents, 18 and 19 in Exhibit No. 3, the sole source of your understanding of what happens to polypropylene when there's cracking?

A. Well, I think Clave also addressed this, that cracking was associated with these failed meshes that were either infected or extruded or had other complications.

Q. Right. But we've covered now the source of your knowledge of what happens to polypropylene when it cracks. That's Clave, and that's documents 18 and 19 in Deposition Exhibit 3?

A. Those are the studies that I'm aware of.

Q. On page 7 of your report in the middle of the page, there's a paragraph that begins, While the addition of stabilizers to polypropylene. You reference a figure 2(a).

A. That should be figure 1(a). I think that's an error. I don't know that I have a figure 2 in this report.

Q. So figure 1(a) goes back to page 5?

Page 122

A. That's right.
Q. All right. The last sentence of that paragraph begins, At this embrittlement stage, the elongation of the polymer decreases substantially. Does that mean the fiber itself shrinks?
A. No. The elongation is the Y axis on this plot. So the percent elongation is the longest distance you can stretch it before it breaks. So it starts off around 800 percent elongation. You could stretch it out to eight times its initial length.
So then when it becomes embrittled even at very small strains, the material fails because it's become embrittled.
Q. Which leads to adverse events after implantation such as extrusion and chronic pain caused by sclerosis. What is sclerosis?
A. Sclerosis would be hardening of the implant in the tissue.
Q. This is the same phenomenon we talked about a few minutes ago?
A. Yes.
Q. Dr. Guelcher, if there's no reduction

Page 123

in molecular weight, would you agree that there's no degradation of the polypropylene?
MR. JACKSON: Object to the form.
A. Again, I think this is a more complex question. When you measure the molecular weight, you're measuring the molecular weight of the entire material. So if the degradation is occurring at the surface, you may not see it.
It's difficult to probe. So I guess the way I want to answer that is if I go back to the -- if I go back to the Ethicon human implant results where they noted --
Q. That's Tab 18?
A. I believe it's Tab 18. If I go back to that one, they mentioned the cracked surfaces were easily wiped off and deposited on a KBR window for IR. The surface scrapings had the handling consistency of a waxy snow.
Then they noted that the surface scrapings were melted at 147 and 156 degrees on a hot stage, and this is the melting range previously observed for oxidatively degraded polypropylene.

Page 124

So what I would say is if you took the entire suture and measured -- it depends on what you're probing and measuring. If you're measuring the molecular weight of the entire suture, because the surface layer doesn't represent the entire volume, you may not see a difference.
But by actually probing that surface layer like they did in this experiment, you would see that it has a lower molecular weight. But if you measure the bulk molecular weight, you may not see it.
That's what I was saying is you would use -- molecular weight measurements are very effective and useful. It's just you have to make sure you're sampling the degraded region of the polymer correctly.
Q. If you go back to page 5 of your report --
A. Right.
Q. -- you have more than a 20 percent reduction in molecular weight before you have embrittlement, don't you?
A. Yes. That was a film, you know, so

Page 125

it's a different -- it's different than -- I mean, these experiments were specifically designed to test this idea. So I don't know that you would necessarily see the same thing in a suture.
Q. Okay. You've not tested it in a suture?
A. No. I guess what I'm saying is molecular weight -- to clear up what I was saying earlier, molecular weight is very important. It's just sampling that degraded layer by molecular weight analysis can be very difficult to do. That's why we like methods like XPS because you can use smaller amounts.
MR. THOMAS: Let's go off the record for a second.
(A break was taken from 12:27 to 1:43 p.m.)
Q. (By Mr. Thomas) Dr. Guelcher, has Dr. Dunn submitted any invoices for your time in this case yet?
A. I don't know if he's submitted invoices to the attorneys. I've submitted invoices to him, but I don't know that he's

Page 126

submitted them to the attorneys.
Q. How many invoices have you submitted?
A. I believe one.
Q. Okay.
A. I can't remember.
Q. If you look at Exhibit No. 1, which is your expert report in this case, how much time did you have in this case prior to the time that you completed Exhibit No. 1?
MR. JACKSON: Object to the form.
A. I don't remember.
Q. (By Mr. Thomas) The time that you have in this case prior to the time that you completed Exhibit No. 1 would be reflected in your billing records?
A. I believe it would.
Q. Okay. From the time that you completed Exhibit No. 1, what additional work have you done in this matter since that time?
A. I reviewed the documents. I wrote the rebuttal report. I met with the attorneys and Dr. Dunn to discuss the documents.
Q. Now, the documents that you've reviewed after Exhibit No. 1, what documents

Page 127

were those?
A. Well, the ones in Exhibit No. 3, I guess. Yeah, this one.
Q. The documents that are in Exhibit No. 2 are the documents that go with your first report; correct?
A. Yes. I reviewed those again too.
Q. Did you review those before you did your report?
A. Yeah. I mean, I wrote the report from those documents. I can't remember how much I reviewed every one, but they were all part of the --
Q. Again, the goal of the deposition Exhibit No. 2 is to capture all the documents upon which you relied for the opinions you express in your original report; correct?
MR. JACKSON: Object to the form.
A. Yes.
Q. (By Mr. Thomas) After you completed your original report, reviewed the documents that were in Exhibit No. 2, you said that you reviewed additional documents. We've talked earlier today about the documents in Exhibit

Page 128

No. 3. When did you review the documents in Exhibit No. 3?
A. Last week.
Q. Okay. And the documents in Exhibit No. 3 is your best effort at identifying all the documents upon which you rely for your rebuttal report which is Exhibit No. 5 that I got this morning; correct?
A. Right.
Q. All right. Now, other than reviewing the documents for Exhibit No. 2 and the documents for Exhibit No. 3, what other work have you done in this case?
A. Well, I wrote the reports.
Q. Right.
A. I reviewed the documents. I --
Q. When you say you reviewed the documents, is your review limited to the documents in Exhibits 2 and 3?
A. There were other documents I went through as well. They're all listed -- all the reliance documents that are listed in the report. I mean, they're all --
Q. That's where I want to ask you about

Page 129

it. If you go to page 11 of Exhibit No. 1, it says in the second sentence, In addition to my knowledge, skill, training, and experience as an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me. And then there's a list of people.
Did you read all those depositions?
A. No. I didn't read all of them.
Q. Do you know of any of them that you read?
A. I reviewed parts of Dr. Burkley's. I think that's the main one I reviewed.
Q. Any others in the first paragraph there that you recall reviewing?
A. Not that I can remember.
Q. The reason why you reviewed Dr. Burkley was to understand the work he did on the seven-year dog study?
A. Primarily, yeah.
Q. Any other reason that you can recall?
A. He was the scientist at Ethicon that had done most of the work on in vivo performance of the polypropylene, the dog

Page 130

study.
Q. The next paragraph says, I've also considered the following material identified in Exhibit B.
Again, there are documents in Exhibit B that aren't in your two notebooks; correct?
A. Yeah, I think so.
Q. And is it fair to understand that to the extent you identified documents that were important to your opinions, you put those in your notebooks, Exhibits 2 and 3?
A. Right.
Q. In addition, the following Rule 26 reports were supplied to me, and a list of people. These reports were provided after we had reached my opinions in this case.
Did you review any of those Rule 26 reports?
A. No, not much, I don't think.
Q. There's nothing in those Rule 26 reports that have any bearing on the opinions that you're giving today as far as you know?
A. No.

Page 131

MR. JACKSON: Objection to form.
Q. (By Mr. Thomas) Down in heading No. 5, it talks about exhibits which I plan to use as a summary of or in support of opinions?
A. Right.
Q. What photographs do you plan to use?
A. Yeah. I don't have any photographs. I don't have FTIR studies, and I don't have exemplar TVT. Dr. Dunn may have. I don't have those. I didn't rely on those for this report.
It was the Ethicon documents and the papers that we've been talking about, but not the first two.
Q. Other than the graphics in your report, are there any other exhibits extracted from the materials that you reviewed or excerpts from learned treatises and literature that you know that you'll use as an exhibit at trial in this case?
A. I don't know. I mean, I haven't thought about preparing for trial. So I don't know what -- I mean, I could use information in those papers to prepare slides. It's hard to say, not having done that.

Page 132

Q. Do you know when trial is scheduled in this case?
A. I don't.
Q. Compensation is listed at $275 an hour for review and study, $350 per hour for deposition and trial testimony time.
How much time have you billed Dr. Dunn for, as of today?
A. I don't remember how many it's been.
Q. Have you been paid yet?
A. I can't remember when I submitted the reports. I may have been paid something for writing a report, but I can't remember when those invoices were submitted.
Q. Are you paid yourself $275 an hour, or is that time that's billed to Dr. Dunn's company and you're paid something different?
A. So Dr. Dunn bills all the effort at 275 or 350 through his company, and he pays me 200 as a subcontractor through his company. So I'm not an employee, but I'm a subcontractor of his company.
Q. Okay. So you receive $200 an hour whether it's review and study or whether it's

Page 133

deposition and trial time?
A. It's $200 for review and study and 275 for deposition and trial testimony.
Q. When you and Dr. Dunn discussed working on the Ethicon mesh cases, and you decided between the two of you the scope of the work that you would do, what was the scope of the work that Dr. Dunn would do?
MR. JACKSON: I'm going to object as asked and answered.
A. I can't speak for Dr. Dunn, but certainly he has expertise in polymer science. So I think he's speaking to the auto-oxidation of polypropylene.
He has expertise in product design. So he was looking at failure modes and effects analysis. He was looking more at those questions.
Q. (By Mr. Thomas) Did you share your report with Dr. Dunn before you finalized it?
A. I don't remember. I know I sent him a copy of the final one. We've discussed it, but I don't know if I sent a draft or something to him.

Page 134

Q. Did you discuss your work on your initial report with Dr. Dunn as you were doing the work?
A. I believe so. I don't quite remember what we talked about prior to writing the report.
Q. When you wanted materials to review in connection with the work that you were doing in this project, did you speak with Dr. Dunn or to counsel?
A. I spoke with Dr. Dunn. Dr. Dunn, through his company, handles all those types of transfers with counsel.
Q. Are you currently engaged in any projects with Dr. Dunn and any other expert in this litigation that is a research project on meshes used in the pelvic floor?
A. So are you talking expert witness in litigation, or are you talking about research projects?
Q. Research projects.
A. We are.
Q. And how many projects?
A. With Dr. Dunn, there's one.

Page 135

Q. And are there projects with other experts?
A. There is. There's a project with Dr. Iakovlev.
Q. What is the project with Dr. Dunn?
A. The project with Dr. Dunn is looking at the characterization of explanted mesh and also the in vitro degradation of mesh for polypropylene.
Q. In vitro degradation?
A. Right.
Q. And what kind of explanted mesh are you characterizing?
A. Well, it's from one of the AMS cases. It's polypropylene mesh. I don't remember the exact name of it, but it's a name that's broad.
Q. What's the nature of the work that you're doing?
A. We're characterizing the surface of the material by XPS.
Q. How many explanted meshes do you have?
A. There are several. I don't remember the exact number.

Page 136

Q. Are they all AMS meshes?
A. I believe they are.
Q. And where did you obtain the meshes?
A. From Dr. Iakovlev.
Q. Do you know where he obtained them?
A. I'm not exactly sure. I mean, they came from the hospital, I believe, that treated the patient. But I don't know exactly which hospital. I don't remember.
Q. Are you and Dr. Dunn in possession of the explants now?
A. I don't know. Dr. Bridget Rogers at Vanderbilt ran the XPS maybe a month ago. I don't know who has them now, if we still have them or if he sent them back.
Q. Who handled the meshes when they were here at Vanderbilt?
A. I believe Dr. Rogers.
Q. Do you know how the explants were received, in what form?
A. They were received as dried fibers.
Q. Do you know who was responsible for the preparation of the explanted mesh samples?
A. Dr. Iakovlev.

Page 137

Q. Did you have any -- do you and Dr. Dunn have any involvement in how those samples will be prepared for XPS testing?
A. Yes. We discussed that with Dr. Iakovlev.
Q. What kind of parameters did you discuss with Dr. Iakovlev about preparation of these samples?
A. We talked about this earlier. I believe they were shipped in saline and then desiccated by Dr. Iakovlev. And then one group, he sent desiccated; another group, he scraped off the degraded material on the surface.
Q. What is the question that you and Dr. Dunn are trying to answer by characterizing these explanted meshes?
A. We're looking for evidence of bound oxygen on the surface that would be indicative of oxidation of the polypropylene mesh.
Q. Is XPS the only test that you're conducting on these explanted meshes?
A. That's all we've done so far. We're considering others. But so far, we've done XPS.

Page 138

Q. And what will the XPS hopefully show? What will this test tell you about the explanted meshes?
MR. JACKSON: Object to form.
A. Well, it would tell you whether there's oxygen bound with carbon on the surface.
Q. (By Mr. Thomas) Is it able to quantify or just detect presence?
A. Quantify.
Q. And in what amounts or quantification would the oxygen bound to carbon be significant in the analysis of oxidation of explanted mesh?
A. Any oxygen would be significant. As Fayolle teaches, it doesn't take much on the surface to catalyze the oxidation of the material.
Oxygen shouldn't be there. It's a hydrocarbon. So any bound oxygen in the material would have to be a result of oxidation. So anything that we found would be significant.
Q. What efforts were made to clean the mesh prior to the XPS testing to remove any

Page 139

other materials that didn't belong there?
A. Well, we discussed that too. So Dr. Iakovlev mainly desiccated the residual tissue. And then one group he sent that had just been desiccated, and the other group he scraped to make sure that all the tissue was gone.
Q. I believe you also said that you were looking at in vitro degradation as part of this project?
A. Yes.
Q. Tell me how that fits into your work.
A. I've published two papers on biomaterials in the last several years where we -- Dr. Anderson reported a number of years ago of fluid that's used to simulate the macrophage pocket. So you can immerse the biomaterial in this fluid, and it's similar to essentially bathing the material in the macrophage. So we're considering doing those experiments as well.
I've published a couple of papers on that with polyurethane where we're able to show that it degrades in vitro.

Page 140

Q. Is that the full scope of the work that you and Dr. Dunn are doing?
A. As of right now.
Q. Do you have plans to do additional work?
A. I don't know. We're still discussing it.
Q. Who was involved in this project other than you and Dr. Dunn?
A. Dr. Iakovlev.
Q. Who is funding this project?
A. We're discussing that right now.
Q. Is anybody funding it now?
A. The explant work was paid for by the litigation.
Q. Does that mean you've received payment from counsel for the plaintiffs in the AMS litigation?
A. Dr. Rogers did for the XPS experiments.
Q. Any other source of payments? Have you received any compensation for your work on this project?
A. Yes. I mean, it's billed, but I

Page 141

didn't actually do the XPS experiments. I've discussed them with Dr. Rogers and Dr. Dunn, and I included it in other reports. So I've been paid for that part of it.
Q. Okay. And is the research project that you're doing with Dr. Iakovlev different than the one you're doing with Dr. Dunn?
A. Dr. Iakovlev's project relates to a number of polypropylene explant materials. They come from a variety of sources like hernia mesh, pelvic floor mesh, where he sees the surface degradation, primarily focusing on histology and microscopic assessment. So it's more qualitative pathology-focused.
Q. Who is working with you and Dr. Iakovlev on that project?
A. Dr. Dunn is involved as well, not as much.
Q. And how many explants are involved in this project?
A. I'm not sure. It's more than ten, I think. I don't remember the number.
Q. Do you know whether any Ethicon explants are involved?

Page 142

A. I don't.
Q. What is Dr. Dunn doing on this project?
MR. JACKSON: Object to the form.
A. Mostly consulting.
Q. (By Mr. Thomas) What are you doing on this project?
A. I had some discussions with Dr. Iakovlev about staining for things like myeloperoxidase to show evidence of active macrophages at the site, similar to what I've done with the other materials I've worked with.
Q. What would the staining of the meshes to show active macrophages at the site show you?
A. It would show that there's secretion of myeloperoxidase, which is an enzyme that is involved in these reactive oxygen species. So it would show the presence of that enzyme and provide evidence that macrophages are at the material surface secreting these reactive oxygen species that can promote oxidation of the polymer.
Q. What's the status of the work that

Page 143

you're doing with Dr. Iakovlev on these polypropylene explant materials?
A. He submitted a presubmission inquiry to Nature Biotech.
Q. I'm sorry, I don't know what that means.
A. Nature Biotechnology is a scientific journal. Dr. Iakovlev submitted a presubmission inquiry regarding its suitability for publication in that journal. As far as I know, he's waiting to hear from the editor.
Q. Has any work been conducted on this project while this request is pending?
A. Not in the past week or two. We've been waiting to hear back.
Q. Prior to that time, had you done any initial work on analyzing these polypropylene explant materials?
A. No. I assisted Dr. Iakovlev with writing, editing the draft.
Q. The draft request?
A. The manuscript, yeah, the presubmission inquiry.
Q. Is there a manuscript in draft?

Page 144

A. It's a presubmission inquiry, so it's basically an abstract of figures.
Q. So there has been work conducted and data collected so far?
A. Yes.
Q. That's what I want to know. What kind of work have you done and data you've collected for this project?
A. Well, so Dr. Iakovlev did the data collection. There's histological staining, staining of histological sections. There's microscopy showing the presence of a degraded layer on the surface.
Q. Is that light microscopy or SCM?
A. Both, polarized light microscopy, SCM. There's another type of imaging technique he used as well. It's all imaging in histology.
Q. What is the question that this paper seeks to answer?
MR. JACKSON: Object to the form, asked and answered.
A. Well, the paper is directed toward providing evidence that polypropylene degrades

Page 145

in vivo by an oxidative mechanism.
Q. (By Mr. Thomas) And who has funded the project with Dr. Iakovlev?
A. I don't know. I think some of the samples have been evaluated in the course of the litigation. So certainly his time would be paid for by the attorneys, plaintiffs' attorneys. But I don't know the details of that.
Q. How much time have you spent on this project with Dr. Iakovlev?
A. Maybe ten hours or so. It's hard to say.
Q. Have you been paid for your time in that project?
A. For parts of it. So I visited Dr. Iakovlev in Toronto as part of the pending litigation. I was paid for that. But for writing the paper, I can't remember if I charged for that or not.
Q. What responsibility did you have for the writing of the paper?
A. Well, Dr. Iakovlev wrote the draft. I edited it. It talks more specifically about

Page 146

surface degradation. Dr. Iakovlev is a pathologist, so my contribution is more on the material science, chemistry, the things described in my report.

Q. The work that you and Dr. Dunn are doing with the AMS polypropylene explants where you're analyzing the surface of the material by XPS, are there plans to publish that research?

A. We would like to publish it, but we're not as far along as Dr. Iakovlev is.

Q. What laboratory is doing the imaging that Dr. Iakovlev is doing for the polypropylene explant materials?

A. I don't know where he's doing it. I presume he's doing it at his university in Toronto.

Q. Is any of the work on the explanted meshes in the polypropylene explant study by Dr. Iakovlev being done at Vanderbilt?

A. No.

Q. And the XPS work and the work with Dr. Dunn has been done by Dr. Rogers at Vanderbilt?

A. Yes, that's right.

Page 147

Q. Are you involved in any research or projects to identify a better material for use as a medical device in the pelvic floor?

A. No.

Q. Have you done any work in this litigation about a suitable alternative device for the treatment of stress urinary incontinence that is equally safe and effective as the Ethicon TVT device?

MR. JACKSON: Objection to form.

A. Again, I was -- my report, my intent was to review the in vivo performance of polypropylene and not look at alternative devices.

MR. THOMAS: Am I going to get the time sheets today?

MR. JACKSON: I'm actually waiting on a response to my e-mail. But the last I heard is that these were included in our objections to the request for production attached to the deposition.

MR. THOMAS: Really?

MR. JACKSON: That's the last response I got, but I am actually waiting

Page 148

on another one. But that's what I've got at this point.

Q. (By Mr. Thomas) Let's go back to your original report, page 8, the paragraph that begins, Finally with respect to the idea, the next sentence reads, These stresses cannot only act as catalysts for oxidative degradation, they can alter the properties of the mesh itself.

What properties of the mesh are changed by the stresses that you discuss in that paragraph?

A. I'm just going to read it again.

Q. Sure.

A. I think what I'm saying here is that the antioxidants basically guard against -- antioxidants are designed to protect against oxidation. So mechanical stresses on the material can sort of exacerbate these effects.

Mechanical loading of the mesh pelvic floor environment is different, say, than the suture. That can cause changes in the degradation and response of the material. That's what I'm really trying to say there.

Page 149

Q. Help me out a little bit. I don't really understand that. They can alter the properties of the mesh. What properties of the mesh can be altered?

A. Strength. It's elongation. These changes in the polypropylene are happening over time. They can change as mechanical properties which is toughness, embrittleness, these things we've been talking about.

Q. Does it include tensile strength?

A. Yeah. Tensile strength would be another mechanical property that could change over time due to oxidative changes.

Q. Okay. So you have tensile strength, you have elongation, you have toughness. What other physical properties of the mesh can be altered by oxidative degradation?

A. I think basically it's the embrittlement -- it's going to become more brittle, less tough. The strength could change. Those are the -- that's what I think of when I think of embrittlement.

Q. Are those the results of the oxidative degradation that you discuss in this

Page 150

paper?
A. Yes.
Q. It's those changes in the physical properties that you just identified that compromise the ability of the mesh to perform its function in the body; is that fair?
A. Yes. I believe that those changes in -- the changes in the composition of the polymer due to the oxidation combined with mechanical forces in the environment of the pelvic floor can cause the mesh to change over time.
Q. And it's those changes in strength, elongation, toughness, embrittlement that you conclude compromise the ability of the mesh to perform its function in the pelvic floor?
A. I think that's part of it.
Q. What else is there?
A. I think as I've been saying in the report, it's really the embrittlement of the mesh is what's causing it to change over time and lead to extrusion and these types of problems.
Q. Anything else?

Page 151

A. I think that's . . .
Q. Let's go to page 10 of your report, please. When you're considering the use of a biomaterial for implantation in a human body, do you consult that material safety data sheet?
A. That's one piece of information. The materials that I'm making, we don't -- they're experimental. So we don't have material safety data sheets.
But for an established material like polypropylene, that's one factor I would look at, is what the MSDS is saying about the material.
Q. Is it normally part of your business when you start working with a material that's going to be implanted in the human body, is it your practice to go to the material safety data sheet to see what it says about that material?
MR. JACKSON: Object to the form.
A. That's typically what we do whether it's in the human body or not. If we're using it in the laboratory if there's a possibility of someone being exposed to it, we keep a file of the MSDSs for all the materials we're using

Page 152

in the lab.
Q. The reason why you keep MSDS sheets for materials in the lab is in the event somebody in the lab is exposed to that material while handling it; correct?
MR. JACKSON: Objection to form.
Q. (By Mr. Thomas) Is that true?
A. Yeah. That's why we have them.
Q. The reason why you have the material safety data sheets is not to determine what the clinical impact of implanting those materials may be in the human body?
A. I think it's something that should be considered. I mean, if it says on the MSDS it's incompatible with strong oxidizers and you know that part of the cellular response is materials that secrete strong oxidizers, that's something that should be considered.
Q. In your judgment, what does a strong oxidizer mean? What's relevant in terms of strong for purposes of degradation to polypropylene mesh?
A. Well, molecular oxygen will oxidize polypropylene at elevated temperatures.

Page 153

Stronger oxidizers such as hypochloric acid and peroxides listed here are stronger oxidizing agents than chlorine.
These are all stronger oxidizing agents than molecular oxygen. That's what I'm referring to when I say reactive oxygen species.
Q. What strength chlorine is required to degrade polypropylene that has antioxidants added to it?
MR. JACKSON: Objection to form.
A. I mean, that's the problem with designing these implants for permanent implantation. It's very difficult to predict what dose of antioxidant is going to be required to protect every patient from this oxidation.
Q. (By Mr. Thomas) Do you have an opinion about how much chlorine would be required to degrade Prolene polypropylene that's been treated with an antioxidant package?
MR. JACKSON: Objection to form.
A. I think you can't just parse out.

Page 154

These are reactive oxygen species. There's a number of different molecules that are secreted by inflammatory cells that have been shown in Ethicon studies and in published papers to cause surface degradation of polypropylene.

So we know that what the cells secrete is enough to oxidize the propylene. It's been observed in several studies.

Q. My question is a little different. Do you have an opinion as to the amount of any of these materials, strong oxidizers such as chlorine, peroxides, etc., that are necessary and sufficient to cause the oxidation of Prolene polypropylene?

MR. JACKSON: Objection to form.

A. My answer would be that macrophages secrete sufficient amounts of these molecules. I mean, we know this because it's been observed.

I don't know that anybody has measured or I don't know how you would measure the exact concentration. It's really irrelevant. It's not being done outside the body. It's being -- you know, Dr. Anderson has

Page 155

published this solution that's been shown to simulate the composition of that macrophage pocket.

But, again, it's a very complex reaction. There's a number of species involved.

Q. One of the things you would like to know is the amount of oxidizers that may compromise polypropylene so that you can modify your additive package to resist that oxidation; fair?

MR. JACKSON: Object to the form.

A. Dr. Anderson has come the closest to describing it as a mixture of cobalt and peroxide that simulates -- I've published a few papers on this.

Q. (By Mr. Thomas) You have or he has?

A. Well, I have. I don't know if my paper is in here or not. It may not be. Dr. Anderson is the first to publish it. It's not in here. Let's see if it's in the other one.

MR. JACKSON: Are you looking for your publications?

Page 156

THE WITNESS: Yeah. It's in my paper.

MR. JACKSON: It's referenced as footnote 9.

THE WITNESS: Yeah. It says "document not available."

A. I'm just checking Anderson's review to see if he tells what it is in here as well.

Well, I don't remember the exact composition of the solution. But he's published a number of papers, and we've used it as well. It's a fluid that can be used to simulate the macrophage pocket in vitro.

Q. (By Mr. Thomas) That's in the context of the polypropylene?

A. No. Other people have cited this as well. It's an in vitro model for oxidative degradation.

Q. You've talked about Dr. Anderson many times. The one study that we've marked -- is it cited in your paper?

A. It's No. 8.

Q. Is it Exhibit 8?

A. I don't know what the exhibit is.

Page 157

It's No. 6.

Q. Have you worked with Dr. Anderson before?

A. I've not worked with him. I know him professionally.

Q. Okay. So when you cite to Dr. Anderson, it's based on your knowledge of his studies and conversations that you've had with him personally as opposed to work that you've done with him on studies?

A. It's mostly through citations. He's very well known in this area of foreign body response. That's his area of expertise. He's very well known in that field.

Q. Now, we talked about Exhibit No. 6 earlier, and I understood that the reason why you cited that paper was for discussion of the foreign body response to implanted materials; correct?

A. Yes.

Q. What specifically is it about the Anderson paper that's important to your opinions?

A. There's a number of papers by other

Page 158

researchers as well. This is, I think, a particularly well written concise review summarizing his 30 years of work in this area. So it's -- I would say that he's a key thought leader in the field, and this is a very nicely written paper and it's useful for citing.

Q. Let's go to 2.4 of Exhibit 6 which is the Anderson paper.

A. Okay.

Q. And the heading is Consequences of Foreign Body Giant Cell Formation.

A. Right.

Q. Right in the middle of that paragraph, it says, For example, additional polymers such as polypropylene used in artificial joints or polypropylene used as a suture material may undergo surface oxidation by the ROIs.

A. Yes.

Q. Medical devices and prostheses composed of addition polymers usually contain small amounts of antioxidants to inhibit this oxidative processes. Do you see that?

A. Yes.

Page 159

Q. Has Dr. Anderson, to your knowledge, ever written that adding small amounts of antioxidants to inhibit this oxidative process is not sufficient to protect against the degradation of polypropylene?

A. I don't think he's saying here that it works or doesn't work. I just think he's saying that this is what people do.

Q. My question is, are you aware of him writing anywhere that the use of antioxidants doesn't work?

A. Again, he's not saying it works here either. He's not saying it works or doesn't work.

Q. If you go to the next page under figure 3, it says again that these studies clearly identify the importance of the use of antioxidants in these polymers to inhibit the oxidation process that occurs with the foreign body reaction.

A. It says that in the text? Where does it say --

Q. It's under "device failure."

A. Yeah. Which paragraph?

Page 160

Q. It's the paragraph that begins "these studies."

A. Oh.

Q. The paragraph ends with, The chemical and molecular composition of the primary structure of the polyurethane polymer is known to modulate or inhibit the process of environmental stress cracking and degradation. And that's by adding these antioxidants; correct?

A. No. That's not what he's saying at all. I think you're misreading this paragraph.

So he says, These studies identify the importance of the use of antioxidants to inhibit the oxidation process. Okay. So he's saying that people use it.

Then he says, The persistence of the foreign body reaction and the fact that it is present at the interface between the tissue and the device for the lifetime suggests that the oxidation process is continuous albeit at low levels. In general, chemical degradation and physical damage in pacemaker leads most probably have a synergistic effect on the

Page 161

failure of the insulation.

What he's saying in the last paragraph is -- this is what I was talking about earlier. When he says the chemical and molecular composition of the primary structure, "primary structure" refers to the backbone of the polymer.

So a polyether urethane is known to be very sensitive to oxidative degradation and its consequent environmental stress cracking. Polycarbonates or polysiloxane urethanes are less sensitive.

So he's saying that the structure of the urethane backbone, whether it's a polyether or polycarbonate in the polyurethane backbone is a contributing factor to this. He's not talking about antioxidants there.

Q. Is it fair to understand that you consider Dr. Anderson to be one of the leading authorities in understanding the extent to which a foreign body reaction to biomaterials may impact oxidation?

A. I wouldn't say it that way. I would say that Dr. Anderson spent a very long career

Page 162

studying the response to the body through the foreign body reaction to implanted biomaterials. That's what this paper is talking about.

Q. Have you ever had discussions with Dr. Anderson about whether antioxidants added to polypropylene can sufficiently inhibit oxidation of the polypropylene to allow the medical device to perform its intended function?

A. I've not discussed that with Dr. Anderson, but he's not saying that in this statement. He's saying you can add antioxidants to try to help it, but the problem is that reaction is never going to stop. So how do you know how much to add?

Ethicon's own data showed that when they add antioxidants, it's depleted after seven or eight years. So it didn't totally work.

Q. That's in that one study we talked about?

A. Yeah. And I haven't seen any other studies -- in one of the memos, they said that

Page 163

they were looking at this. What reference is that?

Q. It was 18, 19, and 20.

A. I think it was No. 20. They said -- there's a memo, a follow-up to -- I think this was a -- well, the meeting minutes from the Prolene explants.

And, basically, it's summarizing those human explants that I was talking about earlier. And then there's a point on here at the top of page 2, it says, Mr. Burkley is planning to look at the remaining dry explants by IOR. He will also try to see the relationship between the amount of stabilizers added to the polymer and degradation and cracking.

You know, we never -- we couldn't find anything further on that. In a number of these presentations that I have also from Ethicon -- I can pull some of these up. This would be --

Q. That's your rebuttal report. I'm not there yet.

A. I know. But you're asking me

Page 164

about -- what I'm saying is, I'm not seeing any evidence here even in this presentation -- they're talking about oxidation, and there's really nothing here that suggests that these studies, looking at a dose response, how much do you have to dose the polypropylene to protect it from oxidation?

There's no evidence that this was looked at after this document in 1987. We couldn't find anything.

Q. Did you ask anybody?

A. We did. Well, Dr. Dunn, like I said, we talked about it. He talked with the attorneys requesting, but I don't think these documents could be found.

Q. Okay.

A. That's what I know. So the only thing that I know about it is what's in these memos and these presentations where basically they're recognizing that there's oxidative degradation.

But there's really no discussion of, Hey, let's do a dose response study. There's e-mails that say should we look at this. And,

Page 165

again, there's no evidence that I've seen that it's being looked at.

I guess I'm just saying it's unknown and, to my knowledge, it's not been looked at.

Q. Did you ask to see all of the degradation work that Ethicon has in its files related to polypropylene?

A. I believe that Dr. Dunn did. I even think Dr. Burkley was asked -- and I don't know if I have that deposition in front of me.

But I believe that in Dr. Burkley's deposition, he really was talking about the dog study. To our knowledge, there weren't other studies.

(Exhibit 10 was marked.)

Q. (By Mr. Thomas) Let me show you what's been marked as deposition Exhibit No. 10. Deposition Exhibit 10 is a letter from me to counsel in this case enclosing a list of studies about which Ethicon testified at what's known as a Rule 30(b)(6) deposition on various studies that were conducted by Ethicon over the years.

And if you look at page 3 of Exhibit

No. 10, there is a topic known as "degradation."
A. Uh-huh.
Q. And I take it that other than the dog study, you've not seen any of these degradation studies where Ethicon has looked at to the extent to which these -- the Ethicon polypropylene degrades in vivo?
MR. JACKSON: Objection to form.
A. I haven't seen these studies.
Q. (By Mr. Thomas) Okay.
A. This is just a list of --
Q. They're available.
MR. THOMAS: Let's go off the record, please.
(A break was taken from 2:41 p.m. until 3:09.)
MR. THOMAS: While at recess, I've had a number of conversations with counsel for the plaintiff about the unavailability of the time records that are the subject of the deposition as well as the late service of the rebuttal report and the anticipated production of a rebuttal report for Dr. Dunn

whose deposition is scheduled for tomorrow.
Counsel and I have agreed that we will stop the deposition of Dr. Guelcher today to resume at a later date; at which point, I will be able to inquire about the billing records which will be produced as well as the scope of the rebuttal report.
In addition, counsel has agreed to talk to me tomorrow about a date for Dr. Dunn; at which time, we will find a date hopefully to resume Dr. Guelcher and to complete Dr. Dunn in a day, the goal being that we only have one day for Dr. Dunn for both his initial report and whatever rebuttal report he prepares so that we get this done as efficiently as we can. I think that's the scope of the agreement.
MR. JACKSON: You have represented it as I understand it.
MR. THOMAS: That's all. Thank you, Dr. Guelcher.
FURTHER THIS DEPONENT SAITH NOT.
(Deposition adjourned at 3:10 p.m.)

CERTIFICATE OF COURT REPORTER

I, Marilyn Morgan, Licensed Court Reporter and Notary Public for the State of Tennessee, do certify that the above deposition was reported by me and that the foregoing transcript is a true and accurate record to the best of my knowledge, skills, and ability.

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I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter as evidenced by the LCR number and expiration date following my name below.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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SCOTT A. GUELCHER, PH.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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